UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE NATIONAL PRESCRIPTION OPIATE LITIGATION	
This document relates to:	MDL No. 2804
The County of Summit, Ohio, et al. v. Purdue Pharma L.P., et al., Case No. 18-op-45090	Hon. Dan Aaron Polster
The County of Cuyahoga, Ohio, et al. v. Purdue Pharma L.P., et al., Case No. 17-op-45004	

Expert Report of Larry Holifield

May 31, 2019

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I. INTRODUCTION

My name is Larry Holifield. I am the co-founder and Director of Corporate Integrity Services LLC, located at 5846 S Flamingo Road #3170, Cooper City, Florida. I have been retained as an independent expert witness by counsel for McKesson Corporation in In Re National Prescription Opiate Litigation, Case No. 17-md-2804, before the U.S. District Court for the Northern District of Ohio.

I understand that McKesson Corporation and other defendants in the above-referenced litigation may use my expert testimony at trial.

I prepared this report to comply with Rule 26(a)(2) of the Federal Rules of Civil Procedure. This report summarizes my current opinions, which are subject to change depending on ongoing discovery and additional information. My opinions in this report are based upon my training, education, and experience, as well as my review of documents in this case (as identified in Appendix B). My opinions set forth in this report are stated to a reasonable degree of certainty.

For trial, I may prepare visual aids to demonstrate various aspects of my testimony.

II. QUALIFICATIONS AND COMPENSATION

I have 37 years of combined law enforcement experience.

From 1970 to 1984, I worked for the St. Louis Police Department ("SLPD"). Throughout my career with the SLPD, I attended training programs to maintain my certification as a police officer in the State of Missouri. I also earned a Bachelor of Arts Degree in Political Science and Legal Justice in 1977 from Maryville University of St. Louis while working with the SLPD.

During my time as a police officer, I worked in a variety of different assignments, including uniform patrol and vice squad until being promoted to narcotics detective in 1976, which I remained throughout my tenure in the department. I received numerous awards at SLPD including Chiefs' Letters of Commendation. I left the SLPD in 1984.

In 1984, I began working for the United States Drug Enforcement Administration ("DEA"). I worked for DEA for 23 years (1984-2007).

During my time at DEA, I served in multiple senior management roles, overseeing the investigation of international drug rings as well as supervising several units that focused on investigating drug diversion.

With tours of duty in Guatemala, Colombia, Mexico, and El Paso, Texas, I spent a significant portion of my DEA career investigating drug trafficking into the United States from Central America, South America, Mexico, and along the Southwest Border. In those roles, I developed expertise on international drug cartels and the flow of illicit drugs across the Southwest Border; I negotiated directly with law enforcement (including Justice Department officials) and numerous government agencies in foreign countries to reform their drug laws; and

I became familiar with the statutes and regulations that DEA relies on to combat drug trafficking and diversion.

From 1987 to 1992, I was a special agent assigned to the Guatemala City Country Office, which covered El Salvador, Belize, and Guatemala. During this timeframe, our office focused on combatting the emergence of new drug trafficking routes through Central America. Colombian drug trafficking organizations had opened these new routes in response to increased law enforcement efforts concentrated on the preexisting routes through the Southeastern United States and the Caribbean.

From 1992 to 1994, I was the Group Supervisor of the Organized Crime Drug Enforcement Task Force ("OCDETF") and reported to the Assistant Special Agent in Charge of DEA's San Francisco Field Office. As the Group Supervisor of OCDETF, I led the investigation of long-term, complex criminal cases. The majority of those cases involved multi-jurisdictional conspiracies of 20-30 people, and almost all had a nexus with Mexico or Colombia. We investigated drug cartels trafficking in crack cocaine, heroin, and methamphetamines. In 1994, I opened the DEA's Oakland, California Office, which also targeted major drug trafficking organizations primarily from Mexico and Colombia.

In 1996, I received a special assignment as liaison to the Central Intelligence Agency in Bogota. Then, in 1998, I received a temporary promotion to become the Assistant Country Attaché to Bogota, Colombia.

In 1999, I returned to DEA Headquarters, at which time my promotion became permanent. I was assigned to be Co-Chair of the Linear Committee, a multi-agency task force that investigates large transnational narcotics traffickers. Although I was familiar with suspicious activity reports ("SARs") used to identify financial links to the illicit drug trade from my prior duties as a Special Agent, I became more familiar with the complex statutes and regulations that mandate SARs by financial institutions during this tour of duty. In this role, I also attained significant knowledge regarding international drug cartels and the illicit sources of drugs abused in the United States.

In 2000, I became Section Chief for Mexico and Central America.

Later in the year 2000, I was transferred to Assistant Special Agent in Charge of the El Paso Field Office. During my time in the El Paso Field Office (2000-2002), I supervised all DEA units operating out of the office, including a diversion unit that consisted of diversion investigators and special agents. As part of my duties, I was responsible for conducting criminal investigations and enforcing compliance with the Controlled Substances Act and its implementing regulations.

From 2002-2006, I was the DEA's Regional Director for Mexico and Central America. During that time, I oversaw two diversion investigators and was involved in high-level meetings and discussions with the Mexican government about drug-related reforms. At the time, my work on drug reform in Mexico was critical to combatting drug abuse in the United States because Mexican laws relating to the sale of drugs like pseudoephedrine had a direct impact on the availability of that substance to the drug cartels that used it to manufacture the methamphetamine

they trafficked across the border. I also continued to interface with and rely upon agents who had special training in suspicious activity reports ("SARs") to identify financial links to the illicit drug trade.

From 2006-2007, I served as the Deputy Special Agent in Charge of the DEA's Miami Field Division and was responsible for all DEA personnel in Florida from the top of the state down to Miami. DEA had a large Diversion Group in Florida at the time and its supervisor reported to me on its activities on a weekly basis. The Diversion Group had personnel in the Miami office and in regional offices in Ft. Lauderdale, Jacksonville, Orlando, and Tampa. In 2006-2007, the Diversion Group was focusing on investigations into internet pharmacies and pill mills, but it also worked with the State of Florida to reform Florida's loose laws concerning licenses to own and operate pharmacies.

In 2007, I retired from the DEA. Throughout my career at DEA, I regularly attended training seminars and courses, including, but not limited to, asset forfeiture training, fingerprinting training, and training provided by CIA related to my international duties. I also received numerous awards while at DEA, including Sustained Superior Service Awards, two DEA Administrator's Awards, and the Warren Medal from CIA.

In 2008, I began working for TurnStone Investigative Group as a Regional Director in Miami, Florida. At TurnStone, I managed and conducted complex domestic and international investigations. I am licensed as a private investigator in the state of Florida.

In 2012, I co-founded Corporate Integrity Services LLC ("CIS"), which is a licensed private investigative agency that provides consulting and investigative solutions to corporate entities, law firms, and individuals. From 2012 to present, I have worked as the Director of CIS. As part of my work at CIS, I frequently advise Mexican and other foreign clients about compliance with US drug laws, including DEA regulations.

My resume is attached as Appendix C.

I am being compensated for my time at my standard rate of $250 per hour. My compensation is not based on the outcome of the litigation.

III. SCOPE OF REPORT

I have been asked to offer opinions on the following topics.

1) DEA's operational structure and its enforcement priorities as they relate to the investigation of illicit drugs and the diversion of legal medications.

2) Registrants' statutory and regulatory obligations related to maintenance of effective controls and controlled substance transaction reporting, including DEA's enforcement of those requirements prior to the Distributor Initiative.

3) The evolution of diversion trends in the United States in the mid-2000s, including the role that rogue internet pharmacies played in that rise, and the resulting efforts

by DEA's Office of Diversion Control to adapt its existing regulations to address these new threats.

4) The options available to enhance DEA's regulatory and enforcement efforts to address new trends in diversion.

5) The effect of additional suspicious order reporting on DEA's efforts to prevent diversion.

6) The contributors to the abuse of illicit drugs and legally produced controlled substances that are outside the control of registrants.

IV. SUMMARY OF OPINIONS

A. DEA has historically prioritized combating illicit drugs and the transnational and domestic criminal organizations who traffic them over combating diversion of prescription drugs.

1. DEA's priorities are evidenced by the personnel it assigns to each task, the organizational structure it has adopted, and the resources it devotes to each task.

a) DEA often assigns diversion investigators without law enforcement powers to investigate diversion of prescription drugs, and assigns DEA agents with law enforcement powers to investigate illicit drugs and related criminal organizations.

b) DEA is organized so that diversion investigators ultimately report through their chain of command to DEA special agents.

c) DEA devotes greater resources and attention to investigate illicit drugs and related criminal organizations than it assigns to investigate diversion of prescription drugs.

2. This prioritization reflects DEA's focus on illicit drugs and related criminal organizations as a more harmful factor in the existing drug crisis than the diversion of prescription drugs.

B. The Controlled Substance Act ("CSA") and DEA's implementing regulations set forth limited—and sometimes vague—requirements related to registrants' responsibility to maintain effective controls against theft or diversion.

1. The purpose of CSA and DEA's implementing regulations is to keep prescription drugs safe within the "closed system of distribution."

2. The DEA's implementing regulations have largely remained the same since 1971.

3. The standards for determining whether registrants are maintaining effective controls against theft and diversion are contained in 21 C.F.R. §§ 1301.71-1301.76.

   a) The regulations state that the determination of whether a registrant has provided "effective controls against diversion" are based upon compliance with "the standards for physical security controls and operating procedures necessary to prevent diversion" as set forth in 21 C.F.R. §§ 1301.72-1301.76, e.g., defining the required thickness of the concrete surrounding a controlled substance vault, requiring restricted access to controlled substance processing areas, etc.

   b) The only due diligence of a customer that a registrant is required to conduct under the regulations is a "good faith" effort to ensure the customer is registered to possess controlled substances. The regulations do not state that a registrant must conduct any other investigation of its customers.

   c) The only requirements related to "suspicious orders" under the regulations is that a registrant must implement a system to identify and report "suspicious orders" to DEA.

   d) The regulations do not state that a registrant must investigate "suspicious orders" or halt them prior to shipment.

4. My opinions regarding the CSA and DEA's implementing regulations are consistent with my experiences supervising diversion units. The units' inspected pharmacies to ensure they were secured against theft and had accounted for their inventory of controlled substances. The units also reviewed registrants' suspicious order monitoring programs for compliance.

C. New diversion trends in the mid-2000s demonstrated the inadequacy of the existing DEA regulations; DEA responded by attempting to stretch the 1971 regulations to address the new problem.

1. The unprecedented rise of rogue internet pharmacies, and later pills mills, were the primary diversion threat in the mid- and late-2000s.

2. DEA was under significant pressure to address the rise of prescription drug abuse in the mid-2000s.

3. In response, DEA sent a "Dear Registrant" letter in December 2007 that attempted to change the expectations set forth in DEA's regulations.

4. Through these letters, and without support in the CSA or its implementing regulations, DEA attempted to shift its law enforcement role to registrants who did not have at their disposal the law enforcement experience or the many investigatory tools available to DEA, such as administrative subpoenas, search warrants, wire taps, undercover personnel to conduct surveillance, or the ability to seize records and computers.

D. There were other legitimate options available to enhance DEA's regulatory and enforcement efforts to address new trends in diversion that were not implemented.

1. The CSA was not amended to expand the duties of registrants beyond those set forth in the original statute.

2. DEA did not issue any new regulations or revise existing regulations relating to the control of the manufacture, distribution, and dispensing of controlled substances as it is authorized to do under 21 U.S.C. § 821.

3. DEA did not provide specific guidance regarding how to identify "suspicious orders," investigate "suspicious orders," investigate their customers, and/or determine which "suspicious orders" or customers should be rejected.

E. If registrants had filed more suspicious order reports it would not have had meaningful impact on DEA's efforts to prevent diversion.

1. DEA already had information on potential "suspicious orders" in its ARCOS data that it could use to identify possible diversion.

a) Distributors and manufacturers reported all transactions involving purchase or sale of prescription opioid medications to the ARCOS reporting system. ARCOS reporting tools allowed DEA to identify pharmacies that were receiving extraordinarily large volumes of narcotics; DEA did not need registrant's suspicious order reports to do that.

b) DEA did not provide registrants access to ARCOS data. Registrants only gained access to limited ARCOS data in 2018.

2. Only a small fraction of suspicious order reports ever resulted in DEA actions against registrants, and DEA's regular practice was to not respond to the suspicious order reports received.

3. There is no basis to conclude that additional suspicious order reports would have resulted in a meaningful decrease in diversion.

F. Factors outside the control of registrants have contributed to the abuse of illicit drugs and legally produced controlled substances inside Summit County and Cuyahoga County.

1. Drug abuse, including abuse of opioid drugs, existed in the United States prior to the diversion of prescription opioids and will continue in the future regardless of the availability of prescription opioids.

2. The current opioid epidemic is best understood in the context of a decades long drug overdose epidemic that began at least as early as the 1970s and has grown exponentially worse over the years.

3. Although drug trafficking and abuse have been increasing for decades, the abuse of a particular illicit drug is often cyclical, with certain drugs rising in popularity before fading and then spiking again in the future.

4. The drug overdose epidemic is fueled by drug trafficking organizations that have long distributed illicit drugs, including illicit opioids, outside the "closed system of distribution."

5. The introduction of highly potent and dangerous illicit fentanyl from international sources is the primary factor fueling the current drug overdose epidemic.

6. The intentional decisions of individual bad actors—including employees of the plaintiffs themselves—that trafficked illicit opioids or diverted prescription opioids outside the controls of the defendant registrants are also responsible for the opioid-related problems in Cuyahoga County and Summit County.

V. DEA'S OPERATIONAL STRUCTURE AND ITS ENFORCEMENT PRIORITIES

In my personal experience as a 23-year veteran of DEA, the DEA has always considered illicit drugs and the transnational and domestic criminal organizations that traffic them to be the highest threat to the American public.[1] DEA devotes considerable law enforcement resources to detecting and investigating these criminal organizations and preventing them from trafficking illicit drugs in the United States. In contrast, DEA has treated combating diversion of legally produced controlled substances as a lower priority.[2] DEA's efforts to combat diversion of

[1] U.S. Department of Justice, Office of the Inspector General, Audit Report 12-05, Audit of the Drug Enforcement Administration's Personnel Resource Management and Casework (2011) ("2011 OIG Audit Report") at Executive Summary ("The DEA focuses on disrupting and dismantling Priority Target Organizations (PTO), which are the major drug supply and money laundering organizations that have a significant impact upon drug availability in the United States."); Keith Martin ("Martin") Dep. 214:8-214:19 (testifying that stopping drug cartels has always been one of DEA's priority focuses).

[2] U.S. Department of Justice, Office of the Inspector General, I-2002-010, Review of the Drug Enforcement Administration's Investigations of the Diversion of Controlled Pharmaceuticals (2002) ("2002 OIG Report") at 28 (small minority of all investigators' time is spent on pharmaceutical diversion); 2011 OIG Audit Report at 4 (small minority of all investigators are

legally produced controlled substances generally consisted of using non-law enforcement personnel, *i.e.*, diversion investigators, to investigate registrants to ensure compliance with technical recordkeeping, suspicious order reporting, and physical security regulations.[3]

A. Personnel

DEA has more than 20 field division offices and more than 200 sub-offices located throughout the United States.[4] The staff at DEA field offices are primarily special agents who often do not receive formal diversion training or participate in diversion investigations.[5] But each of the field division offices and some of the sub-offices have a diversion control unit that is staffed by diversion investigators.[6]

Diversion investigator training consists of a 12-week basic course that covers "(1) an overview of diversion control, (2) techniques for diversion investigations, (3) the laws and regulations governing the Diversion Control Program, (4) an overview of chemical diversion control, and (5) criminal investigations."[7] After completing the training course, diversion investigators are assigned to the field.[8]

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devoted to diversion), 73 (737 personnel utilized on diversion cases and 6,436 personnel utilized on illegal drug cases).

[3] 21 C.F.R. § 1301.74 (requiring reporting of suspicious orders); 21 C.F.R. § 1305.12 (requiring completion of DEA Form 222 in triplicate), 21 C.F.R. § 1304.11 (requiring complete and accurate inventories); 21 C.F.R. § 1301.75 (requiring controlled substances to be stored in "securely locked, substantially constructed cabinet").

[4] DEA Domestic Divisions, https://www.dea.gov/domestic-divisions; 2002 OIG Report at 5; U.S. Department of Justice, Office of the Inspector General, I-2006-004, Follow-Up Review of the Drug Enforcement Administration's Efforts to Control the Diversion of Controlled Pharmaceuticals (2006) ("2006 OIG Report") at 8.

[5] Martin Dep. 31:12-23 (testifying that he never received diversion training and did not recall ever working on any diversion investigations while working as a special agent from 1995 to 2004), 64:18-65:22 (testifying that he was unaware of his enforcement agents or group supervisors ever attending special agent diversion training); U.S Government Accountability Office, GAO-11-744, Prescription Drug Control: DEA Has Enhanced Efforts to Combat Diversion, But Could Better Assess and Report Program Results (2011) ("2011 GAO Report"), at 24 (describing diversion training course that is only provided to special agents specifically assigned to diversion control), 11-12 (explaining that only five special agents in 2008 and 141 special agents in 2011 were specifically assigned to diversion control).

[6] 2002 OIG Report at 5.

[7] 2011 GAO Report at 22 (describing training program for diversion investigators).

[8] 2011 GAO Report at 22 ("After the completion of basic training, the investigators enter into duty under a 1-year probationary period with a midpoint review provided after 6 months of duty.").

Diversion investigators are responsible for initiating administrative, civil, or criminal action against suspected sources of diversion.[9] But while special agents have full law enforcement authority, diversion investigators do not.[10] This means that diversion investigators cannot conduct surveillance or undercover work, direct or pay confidential informants, carry weapons, or serve arrest and search warrants.[11] When diversion investigators need these law enforcement activities to build a case, they must request assistance from special agents or state and local law enforcement officers.[12]

In practice, special agents spend only a very small portion of their time working on diversion investigations.[13] This is consistent with my experience in the field and my understanding of DEA's priorities. Special agents, with law enforcement authority, spent the overwhelming majority of their time building cases against illicit drug traffickers, which is the top priority at DEA.[14] In contrast, diversion investigators, without law enforcement authority, focused on conducting investigations of registrants to ensure compliance with the CSA and its regulations, including but not limited to, technical recordkeeping, suspicious order reporting, and physical security regulations.[15] When diversion investigators identified concerns about a

[9] 2002 OIG Report at 14.

[10] 2002 OIG Report at 5.

[11] 2002 OIG Report at 8, 14. In contrast, special agents or "[e]nforcement agents," "carry guns. They have arrest authority, arrest powers. But they investigate all -- all criminal -- all criminal, civil violations of the Controlled Substances Act. They are not limited to what they investigate." Joseph Rannazzisi ("Rannazzisi") Dep. (Day 1) 151:7-12.

[12] 2002 OIG Report at 14.

[13] 2002 OIG Report at 12 n.7 ("DEA officials told us that a reasonable estimate would be 1 to 3 percent of the agent's total time [is spent on diversion investigations]."); 2006 OIG Report at 76 ("[I]n our current review the percentage of special agent time dedicated to pharmaceutical diversion investigations was at most 2.2 percent.")

[14] 2002 OIG Report at 12 n.7 ("DEA officials told us that a reasonable estimate would be 1 to 3 percent of the agent's total time [is spent on diversion investigations]."); 2006 OIG Report at 76 ("[I]n our current review the percentage of special agent time dedicated to pharmaceutical diversion investigations was at most 2.2 percent."); 2011 OIG Audit Report at 73 (showing 737 personnel utilized on diversion cases and 6,436 personnel utilized on illegal drug cases).

[15] 2011 OIG Audit Report at 10 (explaining that diversion investigators "conduct [regulatory] investigations, [at which they] inspect and verify the registrant's records, take a physical inventory of the registrant's controlled substances, and inspect any other items necessary to verify the registrant's compliance with the CSA and its implementing regulations," and also "conduct preliminary investigative work to determine whether [a complaint of diversion] is valid and warrants a full investigation"); 21 C.F.R. 1301.74 (requiring suspicious order reporting); 21 C.F.R. § 1305.12 (requiring completion of DEA Form 222 in triplicate), 21 C.F.R. § 1304.11 (requiring complete and accurate inventories); 21 C.F.R. § 1301.75 (requiring controlled substances to be stored in "securely locked, substantially constructed cabinet"); Martin Dep. 289:19-290:5 (testifying that diversion agents "do not carry weapons" and confirming that they are "more regulatory based than crime based"). For descriptions of diversion investigators' jobs, Thomas Prevoznik ("Prevoznik") Rule 30(b)(6) Dep. (Day 1) 81:12-19 ("A. [A]s as a diversion

registrant's suspicious order monitoring policies they would be raised with the registrant.[16] When diversion investigators identified a potential need for law enforcement activities to investigate diversion, they would submit that request to a supervisor, such as myself, who would then determine whether special agents should be assigned to assist with the diversion investigation or continue with investigations of illicit drugs.[17]

B. Organization

As Assistant Special Agent in Charge of the El Paso Field Office, Regional Director for Mexico and Central America, and Deputy Special Agent in Charge of DEA's Miami Field Division, I received regular reports from supervisors of the diversion teams regarding their investigative activities. As noted above, I would also receive requests from diversion investigators for special agents to assist with law enforcement activities. This is consistent with the overall organizational structure of DEA. Although DEA's diversion control activities are coordinated from DEA headquarters, they are primarily conducted by DEA's field offices, and the operational activities of the diversion control units are overseen by special agents.[18] This is

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investigator, we conduct -- we conduct investigations, whether it's scheduled investigations, where we're out at the registrants' facilities. It's doing administrative investigations, civil investigations, criminal investigations, compliant investigations."); Rannazzisi Dep. (Day 2) 382:12-19 ("Q. So as a diversion investigator, what would you do? A. We would investigate the methods trying to determine why or how those drugs are being removed from the illicit supply chain, how they are getting to the illicit supply chain and investigate and then take action to stop them from happening.").

[16] Prevoznik Rule 30(b)(6) Depo. Tr. (Day 1) 53:24-6 ("It would also be used in our scheduled investigations. That's when we're out at the registrants and we use it to review the suspicious ordering monitoring system that they have in place to ensure that they are actually doing what they say they are going to do."), 289:21-290:20 ("A. Schedule[d] investigation[s] are … a diversion investigator's work plan. So they will be assigned certain registrants that we will go out and inspect their facility, their registration. Q. And is that inspection or visit different from what might be referred to as a DEA audit or are they -- A. They're the same. Q. The same. Got it. And during a scheduled investigation or audit, does the DEA review a registrant's written policies? A. Their protocols? Q. Yes. A. Yes. Q. And if the DEA has concerns about those policies, does it raise those concerns with the registrant? . . . A. To my -- yes, they do.").

[17] 2002 OIG Report at 16 (describing August 2001 memorandum from DEA's Operations Division that "designated an Assistant Special-Agent-in-Charge (ASAC) at each field office to oversee the operational activities of the diversion control program"); 2006 OIG Report at 75 ("Diversion investigators still do not have law enforcement authority and continue to rely on special agent support to conduct critical tasks in criminal diversion investigations."); 2011 GAO Report at 11 ("[Diversion] investigators do not have law enforcement authority . . . . Special Agents . . . assist Diversion Investigators by performing law enforcement functions . . . .").

[18] 2002 OIG Report at 16 (describing August 2001 memorandum from DEA's Operations Division that "designated an Assistant Special-Agent-in-Charge (ASAC) at each field office to oversee the operational activities of the diversion control program"); Prevoznik Rule 30(b)(6) Dep. (Day 1) 58:15-20 ("Q. So is it fair to say that the primary purpose then of your current unit,

consistent with diversion investigations being treated as a lower priority compared to investigations of illicit drug trafficking organizations.

C. Resources

DEA devotes greater resources and attention to investigating illicit drug trafficking than it devotes to investigating diversion of legally produced controlled substances. Historically, in the period 1997 to 2001, DEA spent less than 10% of its total investigative time on investigations of controlled pharmaceuticals and more than 90% of its total investigative time on investigations of illicit drugs.[19] During that same time period diversion investigators made up less than 12% of the total number of investigators at DEA.[20] The percentage of all investigators devoted to diversion cases as opposed to illicit drug trafficking cases remained below 12% through at least 2010.[21] This is consistent with diversion investigations being treated as a lower priority compared to investigations of illicit drug trafficking organizations.[22]

In my experience, DEA focused its resources on combating illicit drugs and related criminal organizations over diversion of prescription drugs because illicit drugs are a more harmful factor in the existing drug crisis than the diversion of prescription drugs. In setting funding and priorities for DEA, Congress, the President, the Attorney General, and the Administrator of DEA have determined that criminal organizations that traffic illicit drugs are the most significant factor in the existing drug crisis.

VI. REGISTRANTS' STATUTORY AND REGULATORY OBLIGATIONS

As a 23-year veteran of DEA, I am familiar with the Controlled Substances Act ("CSA") and the related regulations. I have reviewed portions of the CSA and related regulations in preparing my expert opinion.

A. Overview of Controlled Substances Act and Closed System of Distribution

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the pharmaceutical investigations section, is to provide support to the field and their various investigations? A. Correct.").

[19] 2002 OIG Report at 12, 28.

[20] 2002 OIG Report at 11.

[21] 2011 OIG Audit Report at 73 (showing 737 personnel utilized on diversion cases and 6,436 personnel utilized on illegal drug cases).

[22] Martin Dep. 59:13-60:4 ("Q. … And on diversion, part of the responsibility of the teams that you have working under you [the ASAC of the field office] would be knowing where diversion occurs in your jurisdiction, who is diverting, and what steps DEA will take to stop the diversion, including making sure that DEA does not contribute to the diversion? … A. So, again, the diversion side does not necessarily report to me. They don't like -- they don't tell me what they're doing.").

Congress passed the CSA in 1970.[23] The CSA established a "closed system" of distribution for controlled substances.[24] The DEA is the government agency that controls the closed system of distribution.[25] Only individuals that obtain a registration from the DEA are permitted to manufacture, distribute, dispense, import, or export controlled substances.[26] The

[23] Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub. L. No. 91-513, §§ 100-709, 84 Stat. 1236, 1242-1284 (1970).

[24] 21 U.S.C. § 822 (requiring every person who manufactures, distributes, or dispenses controlled substances to register with the Attorney General); 21 U.S.C. § 823 (mandating that the Attorney General register manufacturers, distributors, and dispensers of controlled substances); 21 C.F.R. § 1301.11 (requiring "[e]very person who manufactures, distributes, dispenses, imports, or exports any controlled substance or who proposes to engage in the manufacture, distribution, dispensing, importation or exportation of any controlled substance [to] obtain a registration"); Improving Predictability and Transparency in DEA and FDA Regulation, Hearing Before the Subcomm. on Health of the H. Comm. on Energy and Commerce, 113th Cong., 113-137 (2014) (prepared statement of Joseph T. Rannazzisi, Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration) at 83 ("[T]he CSA requires the DEA to establish and maintain a system that strictly controls and monitors the flow of controlled substances in the United States, from the point of importation and manufacture, to distribution, dispensing, and finally, disposal. This is the 'closed system of distribution.'").

[25] 21 U.S.C. § 823 (mandating that the Attorney General register manufacturers, distributors, and dispensers of controlled substances); 28 C.F.R. § 0.100 (delegating Attorney General's authority pursuant to CSA to DEA Administrator); 21 C.F.R. § 1301.11 (requiring "[e]very person who manufactures, distributes, dispenses, imports, or exports any controlled substance or who proposes to engage in the manufacture, distribution, dispensing, importation or exportation of any controlled substance [to] obtain a registration"); 21 C.F.R. § 1301.31 (directing DEA Administrator to review applications for registration); 21 C.F.R. § 1301.35 (directing DEA Administrator to issue registrations when appropriate); Rannazzisi Dep. (Day 1) at 49:24-50:1 ("Q. It's true that DEA controls the closed system of drug distribution, right? A. Yes."); Kyle Wright ("Wright") Dep. (Day 2) 297:6-14 ("[A.] I'll try to say it in a nutshell: to maintain, oversee and protect the closed system of distribution at all levels. … Q. Was that the role of the Drug Enforcement Agency [sic], as you understood it in your experience? A. Yes, sir."); Improving Predictability and Transparency in DEA and FDA Regulation, Hearing before the Subcomm. on Health of the H. Comm. on Energy and Commerce, 113th Cong., 113-137 (2014) (prepared statement of Joseph T. Rannazzisi, Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration) at 83 ("[T]he CSA requires the DEA to establish and maintain a system that strictly controls and monitors the flow of controlled substances in the United States, from the point of importation and manufacture, to distribution, dispensing, and finally, disposal. This is the 'closed system of distribution.'").

[26] 21 U.S.C. § 822 (requiring every person who manufactures, distributes, or dispenses controlled substances, or proposes to do so, to register with the Attorney General); 28 C.F.R. § 0.100 (delegating Attorney General's authority pursuant to CSA to DEA Administrator); 21 C.F.R. § 1301.11 (requiring "[e]very person who manufactures, distributes, dispenses, imports, or exports any controlled substance or who proposes to engage in the manufacture, distribution, dispensing, importation or exportation of any controlled substance [to] obtain a registration"); 21 C.F.R. § 1301.31 (directing DEA Administrator to review applications for registration); 21 C.F.R. § 1301.35 (directing DEA Administrator to issue registrations when appropriate); Rannazzisi Dep.

DEA must approve the registration applications from manufacturers, distributors, pharmacies, and doctors before they can handle controlled substances.[27]

The Administrator of DEA is responsible for making the determination about whether to grant a registrant's application because the Attorney General delegated this task to the Administrator of DEA.[28] The Attorney General assigned his powers under the CSA to the Administrator of DEA, including the authority to create or revise regulations to implement the CSA.[29]

B. Registration Requirements under the Controlled Substances Act

DEA is required by the CSA in 21 U.S.C. § 823 to grant the registration applications for controlled substances unless the applications are inconsistent with the public interest (or U.S. obligations under international treaties, conventions, or protocols).[30] The CSA in 21 U.S.C. § 823 provides factors that DEA must consider when making a decision about whether granting the registration application for controlled substances is consistent with the public interest.

(Day 1) at 51:2-8 ("Q. It's true the DEA registers all manufacturers, distributors, pharmacies and doctors that handle Schedule II controlled substances? A. That's true."); Prevoznik Rule 30(b)(6) Dep. (Day 1) at 267:23-268:3 (testifying that the "closed system of distribution" is "the system … which Congress enacted for the authorized handling of controlled substances. So it requires … DEA registration; everybody needs to be registered").

[27] 21 C.F.R. § 1301.31 (directing DEA Administrator to review applications for registration); 21 C.F.R. § 1301.35 (directing DEA Administrator to issue registrations when appropriate); Rannazzisi Dep. (Day 1) at 52:10-22 (confirming that "[w]hen deciding to grant registration [applications] to a manufacturer, distributor, pharmacy or doctor, the DEA inspects documentation from … potential registrants"); Prevoznik Rule 30(b)(6) Dep. (Day 1) at 267:23-268:3 (testifying that the "closed system of distribution" is "the system … which Congress enacted for the authorized handling of controlled substances. So it requires … DEA registration; everybody needs to be registered").

[28] 21 U.S.C. § 823 (mandating that the Attorney General register manufacturers, distributors, and dispensers of controlled substances); 28 C.F.R. § 0.100 (delegating Attorney General's authority pursuant to CSA to DEA Administrator); 21 C.F.R. § 1301.31 (directing DEA Administrator to review applications for registration); 21 C.F.R. § 1301.35 (directing DEA Administrator to issue registrations when appropriate).

[29] 21 U.S.C. § 821 (authorizing Attorney General to "promulgate rules and regulations … relating to the registration and control of the manufacture, distribution, and dispensing of controlled substance"); 28 C.F.R. § 0.100 (delegating Attorney General's authority pursuant to CSA to DEA Administrator); Rannazzisi Dep. (Day 1) 58:21-24 ("The regulation change would be under the authority of the administrator of the Drug Enforcement Administration and Department of Justice."), 59:1-3 ("the final decision [to change a CSA regulation] is [up to] the Department of Justice and the Drug Enforcement Administration leadership").

[30] 21 U.S.C. § 823.

21 U.S.C. § 823 lists the factors that DEA must consider when deciding whether granting the applications of manufacturer and distributor registrants is in the public interest. 21 U.S.C. § 823(b) and (e) list the factors for distributors and require DEA to consider "maintenance of effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels."[31] 21 U.S.C. § 823(a) and (d) list the factors for manufacturers and include "maintenance of effective controls against diversion of particular controlled substances and any controlled substance … compounded therefrom into other than legitimate medical, scientific, research, or industrial channels."[32] Although DEA is required by 21 U.S.C. § 823 to consider the applicant's "maintenance of effective controls against diversion" when deciding whether to grant a registration,[33] § 823 does not create separate obligations for manufacturers or distributors to investigate whether their customers are maintaining effective controls against diversion of controlled substances into illegitimate channels.[34]

In addition to registering manufacturers, distributors, pharmacies, and doctors, DEA has the authority to revoke or suspend the registrations.[35] DEA has the authority to issue an "order to show cause why a registration should not be revoked or suspended."[36] DEA also has the authority to immediately suspend [a] registration where it "finds that there is an imminent danger to the public health or safety."[37]

C. Requirements for "Effective Controls" Outlined in the Regulations

The specific requirements for "maintenance of effective controls" are identified in DEA's implementing regulations, 21 C.F.R. §§ 1301.71-76. 21 C.F.R. § 1301.71(a) explains "[a]ll

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[31] 21 U.S.C. § 823(b)(1) (relating to distributors of controlled substances in schedule I or II), (e)(1) (relating to distributors of controlled substances in schedule III, IV, or V).

[32] 21 U.S.C. § 823(a)(1) (relating to manufacturers of controlled substances in schedule I or II), (d)(1) (relating to manufacturers of controlled substances in schedule III, IV, or V).

[33] 21 U.S.C. § 823(a)(1), (b)(1), (d)(1), (e)(1).

[34] Rannazzisi Dep. (Day 2) 526:19-527:3 ("Q. Okay. Now, within the Controlled Substances Act … the words 'know your customer' does not appear, correct? A. The words 'know your customer' is not in the Controlled Substances Act. Q. And the words 'due diligence' are not in the Controlled Substances Act either, right? A. That is correct."); Demetra Ashley ("Ashley") Dep. 159:20-160:3 ("Q. … Going back to know your customer's customer, to your knowledge, is there any language in the Controlled Substances Act that states that a manufacturer is required to know its customer's customer? A. In the Controlled Substances Act, no. Q. Is that phrase anywhere in the CSA to your knowledge? A. To my knowledge, no."); Prevoznik Rule 30(b)(6) Dep. (Day 1) 209:1-7 ("Q. Now, did the Controlled Substances Act in this time period state that the registrants must know their customer to decide whether an order is suspicious or not? A. It does not have that specific language."); 21 U.S.C. § 823.

[35] 21 U.S.C. § 824 (providing for denial, revocation, or suspension of registrations); 21 C.F.R. § 1301.36 (describing DEA's authority to suspend or revoke registrations").

[36] 21 C.F.R. § 1301.37.

[37] 21 C.F.R. § 1301.36.

applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances."[38] The regulation goes on to explain that, "[i]n order to determine whether a registrant has provided effective controls against diversion, the Administrator shall use the security requirements set forth in Secs. 1301.72-1301.76 as standards for the physical security controls and operating procedures necessary to prevent diversion."[39] The security requirements identified in 21 C.F.R. §§ 1301.72-1301.76 primarily focus on making sure that controlled substances are safe and secure while the controlled substances are in a registrant's custody and control.[40] This focus is consistent with my experiences supervising a diversion unit in El Paso from 2000 to 2002. As reported to me, the diversion unit's primary focus was on inspecting pharmacies to ensure they were secured against theft and had accounted for their inventory of controlled substances. The diversion unit also inspected the registrants' suspicious order monitoring programs.[41] I briefly describe 21 C.F.R. §§ 1301.72, .73, .75, and .76 below, before turning to 21 C.F.R. § 1301.74.

1. Section 1301.72

Section 1301.72 describes the secured areas where controlled substances must be stored in extensive detail. For example, the regulation requires: "A vault constructed after September 1, 1971 … [shall have] walls, floors, and ceilings … constructed of at least 8 inches of reinforced concrete or other substantial masonry, reinforced vertically and horizontally with \1/2\-inch steel rods tied 6 inches on center, or the structural equivalent to such reinforced walls, floors, and ceilings."[42] The regulation goes on to provide various other physical security requirements for registrants who are not physicians.[43]

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[38] 21 C.F.R. § 1301.71(a).

[39] 21 C.F.R. § 1301.71(a).

[40] 21 C.F.R. §§ 1301.72 (describing secured areas where controlled substances must be stored by); 1301.73 (describing safeguard to maintain the security of controlled substances during the manufacturing process); 1301.74 (describing "good faith" registration check required before sending controlled substances to a customer); 1301.75 (describing physical storage requirements for practitioners).

[41] Prevoznik Rule 30(b)(6) Depo. Tr. (Day 1) 53:24-6 ("It would also be used in our scheduled investigations. That's when we're out at the registrants and we use it to review the suspicious ordering monitoring system that they have in place to ensure that they are actually doing what they say they are going to do."), 289:21-290:20 ("A. Schedule[d] investigation[s] are … a diversion investigator's work plan. So they will be assigned certain registrants that we will go out and inspect their facility, their registration. Q. And is that inspection or visit different from what might be referred to as a DEA audit or are they -- A. They're the same. Q. The same. Got it. And during a scheduled investigation or audit, does the DEA review a registrant's written policies? A. Their protocols? Q. Yes. A. Yes. Q. And if the DEA has concerns about those policies, does it raise those concerns with the registrant? . . . A. To my -- yes, they do.").

[42] 21 C.F.R. § 1301.73(a)(3)(i).

[43] 21 C.F.R. § 1301.72(a).

2. Section 1301.73

Section 1301.73 describes various safeguards to maintain the security of controlled substances during the manufacturing process.[44] For example, it directs that "[a]ll in-process substances shall be returned to the controlled substances storage area at the termination of the process,"[45] "[m]anufacturing activities with controlled substances shall be conducted in an area or areas of clearly defined limited access which is under surveillance,"[46] and "[d]uring the production of controlled substances, the manufacturing areas shall be accessible to only those employees required for efficient operation."[47]

3. Section 1301.75

Section 1301.75 describes the physical storage rules that practitioners, such as pharmacists, must follow with controlled substances.[48] For example, it directs that controlled substances "shall be stored in a securely locked, substantially constructed cabinet."[49]

4. Section 1301.76

Section 1301.76 requires that practitioners not employ certain individuals that may be likely to divert controlled substances (e.g., individuals convicted of felonies related to controlled substances).[50] It also requires practitioners to report the "theft or significant loss of any controlled substance."[51] Finally, it requires that practitioners that act as distributors must comply with certain regulations related to distributors.[52]

5. Section 1301.74

a) Requirements in Section 1301.74(a)

Section 1301.74(a) requires a registrant to "make a good faith inquiry" to determine that a customer "is registered to possess the controlled substance."[53] The regulation does not reference "due diligence" or any other investigation that a registrant is required to perform on a customer prior to completing a transaction beyond the "good faith inquiry" as to the customer's

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[44] 21 C.F.R. § 1301.73.

[45] 21 C.F.R. § 1301.73(a).

[46] 21 C.F.R. § 1301.73(b).

[47] 21 C.F.R. § 1301.73(c).

[48] 21 C.F.R. § 1301.75

[49] 21 C.F.R. § 1301.75(a) & (b).

[50] 21 C.F.R. § 1301.76(a).

[51] 21 C.F.R. § 1301.76(b).

[52] 21 C.F.R. § 1301.76(c)-(d).

[53] 21 C.F.R. § 1301.74(a).

registration status.[54] For example, there is no requirement set forth in § 1301.74 requiring a registrant to "know your customers" to "know your customer's customer," or to know who is ultimately prescribing the medications.[55] The regulation also does not require any additional due diligence by registrants other than a good faith inquiry to determine that the customer is registered to handle controlled substances.[56] The regulation also does not require registrants to create or maintain "due diligence" files on their customers.[57]

The scope of the regulatory requirements I describe above is consistent with my experience supervising a diversion unit prior to 2006. While I was Assistant Special Agent in

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[54] 21 C.F.R. § 1301.74(a).

[55] 21 C.F.R. § 1301.74; Rannazzisi Dep. (Day 2) 534:4-9 ("Q. Okay. Now, in that section [21 C.F.R. § 1301.74], does the word or words 'know your customer' appear? A. No, ma'am. Q. Do the words 'due diligence' appear in this regulation? A. No, ma'am."); Prevoznik Rule 30(b)(6) Dep. (Day 1) 212:1-4 ("Q. Today, does the regulation explicitly reference knowing your customer? A. No."), 325:1-12 ("Q. But neither the statute nor the regulation says explicitly that manufacturers need to know their customers' customers, do they? A. It does not say that explicitly. But it does say that you need to guard against diversion. Q. Has the DEA ever provided guidance to the industry in writing informing registrants that they are to know their customers' customers? A. Not that I'm aware of.").

[56] Rannazzisi Dep. (Day 2) 534:4-24 ("Q. Okay. Now, in that section [21 C.F.R. § 1301.74], does the word or words 'know your customer' appear? A. No, ma'am. Q. Do the words 'due diligence' appear in this regulation? A. No, ma'am. Q. Do the words 'dispensing data' appear in this regulation? A. No, ma'am. Q. Do the words 'customer questionnaire' appear in this regulation? A. No, ma'am. Q. Do the words 'electronic order monitoring system' appear in this regulation? A. No, ma'am. Q. Do the words 'do not ship' appear in this regulation? A. No, ma'am. Q. Do the word 'dispensing data' appear in this regulation? A. No, ma'am."); Ashley Dep. 215:12-216:4 ("Q. Is [due diligence] explained in the federal regulation, [21 C.F.R. 1301.74]? … A. No."); Wright Dep. (Day 2) 496:8-14 ("Q. So the due diligence that got referenced in your discussion this morning, that is not required by the statute or the regulation, correct? . . . THE WITNESS: It is not mentioned specifically."); 21 C.F.R. §§ 1301.71-.76.

[57] 21 C.F.R. §§ 1301.71-.76; Prevoznik Rule 30(b)(6) Dep. (Day 3) 1218:17-1219:10 ("Q. The DEA has certainly never issued any sort of guidance indicating that registrants must hold on to due diligence files for 15 years, correct? A. Yes. The only guidance I know is it's two years, two years for recordkeeping for the registrant. … Q. But there's no requirement that a due diligence file even be maintained, correct? A. Correct. Q. So the two-year rule does not apply to any due diligence files, per se, correct? A. Correct. I was just pointing out that within the regs, there is records for a two-year period."); Rannazzisi Dep. (Day 2) 555:7-11 ("Q. Is there any requirement in the DEA regulations or guidance to maintain due diligence documentation for a certain period of time? A. There's no requirements."); Wright Dep. (Day 1) 143:2-12 ("Okay. And the exercise that the registrant goes through to do some due diligence to really bear out whether the order is, in fact, truly a suspicious order or not, that due diligence exercise, is there a regulatory requirement to document that due diligence? . . . THE WITNESS: No."); Wright Dep. (Day 2) 496:23-497:4 (Q. And it is the documentation of -- whatever due diligence is done by a company, that may be a best practice, but it is not required by statute or regulation, correct? . . . THE WITNESS: Yes, ma'am.").

Charge of the El Paso Field Office, I supervised a diversion unit and reviewed any law enforcement activities they proposed. In my experience, the focus of diversion units prior to 2006 was on physically inspecting pharmacies to ensure that they were properly securing and accounting for prescription drug medications.

b) Requirements in Section 1301.74(b)

Section 1301.74(b) provides that a registrant "shall design and operate a system to disclose to the registrant suspicious orders of controlled substances."[58] The regulation states that the "registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant."[59] While neither the CSA nor its regulations provide a definition for "suspicious order," § 1301.74(b) states that a "suspicious order may include "orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency."[60]

It is important to understand what is not required by § 1301.74. There is no requirement in § 1301.74 that a registrant make a decision regarding the likelihood that a specific order will be diverted into illegitimate channels.[61] There is no requirement in the regulation that a registrant decide if an order is actually "suspicious" as the public understands that word. It is also critical to understand that the regulation does not require registrants to stop or "block" orders that are "suspicious" under § 1301.74."[62] Nor does the regulation require a registrant to

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[58] 21 C.F.R. § 1301.74(b).

[59] 21 C.F.R. § 1301.74(b).

[60] 21 C.F.R. § 1301.74(b). DEA witnesses have acknowledged that this is a subjective requirement and have been unable to provide comprehensive definitions for suspicious orders. Prevoznik Rule 30(b)(6) Dep. (Day 1) -185:2 ("Q. [I]s it fair to say then that the identification of suspicious orders can be a subjective process. … A. Yeah, it can be subjective."). At least one expert for Plaintiffs has agreed. James Rafalski ("Rafalski") Dep. (Day 1) 404:23-405:2 ("Q. Can reasonable minds disagree about whether or not a particular order is suspicious? A. I think, yes, I would answer yes to that question.").

[61] 21 C.F.R. § 1301.74(b); Rannazzisi Dep. (Day 2) 534:4-24 ("Q. Okay. Now, in that section [21 C.F.R. § 1301.74], does the word or words 'know your customer' appear? A. No, ma'am. Q. Do the words 'due diligence' appear in this regulation? A. No, ma'am. Q. Do the words 'dispensing data' appear in this regulation? A. No, ma'am. Q. Do the words 'customer questionnaire' appear in this regulation? A. No, ma'am. Q. Do the words 'electronic order monitoring system' appear in this regulation? A. No, ma'am. Q. Do the words 'do not ship' appear in this regulation? A. No, ma'am. Q. Do the word 'dispensing data' appear in this regulation? A. No, ma'am."); Ashley Dep. 215:12-216:4 ("Q. Is [due diligence] explained in the federal regulation, [21 C.F.R. 1301.74]? … A. No.")

[62] 21 C.F.R. § 1301.74(b); Rannazzisi Dep. (Day 2) at 534:19-21 ("Q. Do the words 'do not ship' appear in this regulation? A. No, ma'am."); Prevoznik Rule 30(b)(6) Dep. (Day 3) 1154:7-11 ("Q. Mr. Prevoznik, I think we've already established that the regulation does not explicitly say do not ship orders that you report as suspicious, right? A. I agree with that….").

use any particular system,[63] such as a manual or automated system,[64] or even have written policies or procedures with respect to that system.[65]

There is also no requirement in § 1301.74(b) that a registrant must investigate orders that are "suspicious" under § 1301.74.[66] The regulation does not require or even mention "due diligence" or "investigation" of orders from customers that meet the regulatory definition of suspicious orders.[67] There is also no requirement in the regulation that a registrant must create or maintain "due diligence" files from any investigations that a registrant conducts on orders that a registrant identifies as meeting the definition of suspicious order.[68] The regulation makes no mention of "due diligence" files and it does not impose a requirement on how long any existing "due diligence" files must be retained by the registrant.[69] Other DEA retention requirements for

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[63] 21 C.F.R. § 1301.74(b); Prevoznik Rule 30(b)(6) Dep. (Day 1) 180:7-10 ("Q. And the DEA leaves it up to the registrant to design a system that works with its own business model and customer base, correct? A. Correct.")

[64] 21 C.F.R. § 1301.74(b); Prevoznik Rule 30(b)(6) Dep. (Day 1) 180:12-15 ("Q. Does it matter to the DEA whether a registrant reviews orders manually or uses an automated system? A. No, it doesn't matter."); Ashley Dep. 88:11-89:4 ("Q. To your knowledge, does a legally compliant system need to be automated? A. No, it does not.").

[65] 21 C.F.R. § 1301.74(b); Prevoznik 30(b)(6) Dep. (Day 1) 358:21-359:1 ("Q. Does it say anywhere in the relevant regulations that registrants are required to have a written policy with respect to suspicious order monitoring? A. No.").

[66] 21 C.F.R. § 1301.74(b).

[67] 21 C.F.R. § 1301.74(b); Rannazzisi Dep. (Day 2) 534:4-24 ("Q. Okay. Now, in that section [21 C.F.R. § 1301.74], does the word or words 'know your customer' appear? A. No, ma'am. Q. Do the words 'due diligence' appear in this regulation? A. No, ma'am. Q. Do the words 'dispensing data' appear in this regulation? A. No, ma'am. Q. Do the words 'customer questionnaire' appear in this regulation? A. No, ma'am. Q. Do the words 'electronic order monitoring system' appear in this regulation? A. No, ma'am. Q. Do the words 'do not ship' appear in this regulation? A. No, ma'am. Q. Do the word 'dispensing data' appear in this regulation? A. No, ma'am."); Ashley Dep. 215:12-216:4 ("Q. Is [due diligence] explained in the federal regulation, [21 C.F.R. 1301.74]? … A. No."); Prevoznik Rule 30(b)(6) Dep. (Day 1) 212:1-4 ("Q. Today, does the regulation explicitly reference knowing your customer? A. No.").

[68] 21 C.F.R. § 1301.74(b); Prevoznik Rule 30(b)(6) Dep. (Day 3) 1218:17-1219:10 ("Q. The DEA has certainly never issued any sort of guidance indicating that registrants must hold on to due diligence files for 15 years, correct? A. Yes. The only guidance I know is it's two years, two years for recordkeeping for the registrant. … Q. But there's no requirement that a due diligence file even be maintained, correct? A. Correct. Q. So the two-year rule does not apply to any due diligence files, per se, correct? A. Correct. I was just pointing out that within the regs, there is records for a two-year period."); Rannazzisi Dep. (Day 2) 555:7-11 ("Q. Is there any requirement in the DEA regulations or guidance to maintain due diligence documentation for a certain period of time? A. There's no requirements.").

[69] 21 C.F.R. § 1301.74(b); Prevoznik Rule 30(b)(6) Dep. (Day 3) 1218:17-1219:10 ("Q. The DEA has certainly never issued any sort of guidance indicating that registrants must hold on to due diligence files for 15 years, correct? A. Yes. The only guidance I know is it's two years, two

registrants, found in the CSA[70] and in 21 C.F.R. § 1304.04,[71] are limited to retaining inventory and other records related to inventory for two years.

6. Lack of Clarity Regarding What Constitutes a Suspicious Order under Section 1301.74(b).

Under § 1301.74(b), "[s]uspicious orders" are defined to "include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency."[72] What constitutes a suspicious order under § 1301.74(b) is unclear, and the regulation fails to provide sufficient guidance to registrants.[73] No definition of "unusual size" is offered in the regulation.[74] The regulation also fails to provide guidance as to how a registrant can determine if an order is

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years for recordkeeping for the registrant. … Q. But there's no requirement that a due diligence file even be maintained, correct? A. Correct. Q. So the two-year rule does not apply to any due diligence files, per se, correct? A. Correct. I was just pointing out that within the regs, there is records for a two-year period."); Rannazzisi Dep. (Day 2) 555:7-11 ("Q. Is there any requirement in the DEA regulations or guidance to maintain due diligence documentation for a certain period of time? A. There's no requirements.").

[70] 21 U.S.C. § 827(b) ("Every inventory or other record required under this section (1) shall be in accordance with, and contain such relevant information as may be required by, regulations of the Attorney General, … and (3) shall be kept and be available, for at least two years, for inspection and copying by officers or employees of the United States authorized by the Attorney General.").

[71] 21 C.F.R. § 1304.04(a) ("… [E] every inventory and other records required to be kept under this part must be kept by the registrant and be available, for at least 2 years from the date of such inventory or records ….").

[72] 21 C.F.R. § 1301.74(b).

[73] Prevoznik Rule 30(b)(6) Dep. (Day 3) 897:10-23 ("Q. Okay. And I want to make sure that your testimony is clear. When you say whether a suspicious order is subjective, do you mean that it varies from case to case, or it depends on who's looking at it? … [A.] Both, really. It depends who's looking at it and what system do they have that's triggering the suspicious order. So it's whatever that registrant designed, which is specific to that registration.").

[74] Ashley Dep. 146:21-147:11 ("[Q.] What about unusual in Section B, what is meant by unusual size? A. It would be different from the norm of the size that that particular customer typically orders. Q. Different from the norm. So how much of a deviation would make it unusual? A. That would be determined by the distributor or the manufacturer. Q. So is there any threshold for determining whether a deviation is unusual? A. Not that the DEA sets, no. Q. Based on your experience, would you agree that there might be situations where an order is of an unusual size, but the order is not suspicious? A. Yes.").

"unusual size."[75] Determining whether an order is of "unusual size" is a subjective determination,[76] and for example, the determination can vary depending on if the comparison is:

- "An order of unusual size compared to orders of other customers";
- "An order of unusual size compared to orders of a certain subset of customers"; and
- "An order of unusual size compared to that particular customer's historical orders."

DEA offers no guidance to registrants in the regulation on the comparison that should be used by registrants in determining whether an order is of "unusual size."[77] "Unusual size" is also ambiguous because DEA fails to provide guidance as to what level quantitative change constitutes an order of unusual size.[78] The regulation provides no guidance, for example, on whether a 10% increase is "unusual," a 50% increase is "unusual," or if a 100% increase is

[75] 21 C.F.R. § 1301.74(b); Rannazzisi Dep. (Day 2) 535:11-18 ("Q. The phrase 'unusual size,' does this regulation do anything more to explain what 'unusual size' could mean? A. The regulation is 'of unusual size.' That's all it says. Q. So it doesn't do anything to further explain what 'unusual size' means, correct? A. No."); Ashley Dep. 26:16-19 ("Q. Does the regulation … provide guidance as to what constitutes an order of unusual size? A. No.").

[76] Prevoznik Rule 30(b)(6) Dep. (Day 3) 897:10-23 ("Q. Okay. And I want to make sure that your testimony is clear. When you say whether a suspicious order is subjective, do you mean that it varies from case to case, or it depends on who's looking at it? … [A.] Both, really. It depends who's looking at it and what system do they have that's triggering the suspicious order. So it's whatever that registrant designed, which is specific to that registration.").

[77] Rannazzisi Dep. (Day 2) 535:11-18 ("Q. The phrase 'unusual size,' does this regulation do anything more to explain what 'unusual size' could mean? A. The regulation is 'of unusual size.' That's all it says. Q. So it doesn't do anything to further explain what 'unusual size' means, correct? A. No."); Ashley Dep. 26:16-19 ("Q. Does the regulation … provide guidance as to what constitutes an order of unusual size? A. No.").

[78] Rannazzisi Dep. (Day 2) 535:11-18 ("Q. The phrase 'unusual size,' does this regulation do anything more to explain what 'unusual size' could mean? A. The regulation is 'of unusual size.' That's all it says. Q. So it doesn't do anything to further explain what 'unusual size' means, correct? A. No."); Ashley Dep. 26:16-19 ("Q. Does the regulation … provide guidance as to what constitutes an order of unusual size? A. No.").

"unusual."[79] DEA additionally offers no guidance in helping registrants determine whether an order is suspicious.[80] Furthermore, large orders are not necessarily indicative of diversion.[81]

The same lack of clarity attaches to "orders deviating substantially from a normal pattern" and "orders of unusual frequency."[82] The regulations and guidance do not define and provide no explanation for how to determine if an order is "deviating substantially" from a "normal pattern."[83] There is also no definition of or guidance regarding how a registrant should define a "normal pattern," including whether "normal" is defined in comparison of orders for that particular customer, a subset of the registrant's customers, or the registrant's entire customer base.[84] The regulation also does not define what types of changes with respect to a customer ordering "new" types of pharmaceutical products constitutes a substantial deviation from a normal pattern.[85]

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[79] 21 C.F.R. § 1301.74(b).

[80] Prevoznik Rule 30(b)(6) Dep. 292:22-293 ("Q. …[I]f a registrant came to you today and said I am trying to decide whether this order is suspicious, am I correct that the DEA's policy is that the DEA will not provide a yes or no answer to that question? … A. I would be extremely concerned if you as a registrant came to me and asked me to make that determination. Because you are basically telling me that you -- you do not have the ability to effectively -- to maintain effective guards against diversion if you're coming to us with that hypothetical. Which would be grounds for us to revoke your registration."); Rannazzisi Dep. (Day 1) 43:13-23 ("Q. So it was DEA's policy not to tell registrants that an order is suspicious? … A. It was a business decision that would be made by the distributor whether an order was suspicious.").

[81] Patrick Leonard ("Leonard") Dep. (Day 3) 427:14-428:2 ("Q. Have you ever started an investigation related to diversion based solely on the volume of prescription opioids being dispensed. A. No. There's always more factors that are looked at before an investigation is opened. Q. Volume alone can't tell you that something is necessarily wrong? A. No."); Lori Baker-Stella ("Baker-Stella") Dep. (Day 2) 413:5-19 ("Q. My question is, the number of prescriptions alone is not enough to reach a judgment on whether there's overprescribing or not? A. Yes. Q. Have you ever requested a search warrant for a doctor based solely on the amount of prescriptions that the doctor was writing? A. I don't believe I have").

[82] 21 C.F.R. § 1301.74(b).

[83] Rannazzisi Dep. (Day 1) 277:8-22 ("Q. So let me come back to -- to this -- so you gave me your elaboration and further definition of some of the terminology in 21 C.F.R. 1301.74, right? A. Yes. Q. But your elaboration, your further definition of unusual size, pattern, frequency, that's not in the regulation itself, right? … [A.] No. … No, it's not in the regulation.").

[84] 21 C.F.R. § 1301.74(b); Rannazzisi Dep. (Day 1) 277:8-22 ("Q. So let me come back to -- to this -- so you gave me your elaboration and further definition of some of the terminology in 21 C.F.R. 1301.74, right? A. Yes. Q. But your elaboration, your further definition of unusual size, pattern, frequency, that's not in the regulation itself, right? … [A.] No. … No, it's not in the regulation.").

[85] Rannazzisi Dep. (Day 1) 262:22-263:5.

Similarly, the DEA failed to provide sufficient guidance to determine "orders of unusual frequency." DEA again failed to explain whether "unusual frequency" involves a comparison to prior orders of that particular customer, a certain subset of that registrant's customers, or a comparison to that registrant's entire customer base. The regulation also fails to provide guidance on what types of changes in order frequency rise to the level of "unusual frequency." DEA also failed to provide guidance as to the potential overlap between whether an order is of "unusual size," "deviating substantially" from a normal pattern, or an order of "unusual frequency."[86] In fact, Mr. Rannazzisi testified that during his tenure as the head of the Office of Diversion Control, DEA lacked internal guidance as to what orders constituted "suspicious orders" under the regulation.[87]

Around the time of the Distributor Initiative, the lack of clarity in the regulation and the lack of guidance from DEA on the definition on "suspicious orders" resulted in confusion among registrants and led to complaints from registrants on the lack of DEA guidance.[88] This confusion could have been alleviated but for, as discussed in the December 2007 letter from Mr.

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[86] Rannazzisi Dep. (Day 1) at 272:22-273:9.

[87] Rannazzisi Dep. (Day 1) 317:12-22 ("Q. And for clarity, let me focus you on time periods with that same question. Let's say from the 2005 through the time you left DEA in 2016, that is the time period, in that time period of 2005 to 2016, yes or no, did DEA have internal guidance as to what constitutes a suspicious order? …[A.] No.").

[88] Ashley Dep. 58:23-59:6 ("Q. At any time during your tenure at the DEA, did you learn that the distributors were confused about their suspicious order regulations and wanted more guidance from the DEA? A. I can say in speaking with distributors, they expressed that they wanted more clarification. Q. And so you heard that directly from the distributors? A. Yes."); Wright Dep. (Day 1) 120:12-121:3 ("Q. But you did recognize -- and I think your testimony at trial supports this concept -- you recognized that this change from the Excessive Order System to the Suspicious Order System, which was more fluid, would cause confusion in the industry, correct? A. Yes. Q. And that was part of the reason you wanted to do these distributor briefings and go one on one with distributors, right? A. Yes. Q. And there was also concern, as I saw from your prior testimony, that your own DEA agents might be confused by the -- the changes going on within the industry, correct? … A. Yes."). United States Government Accountability Office, "Prescription Drugs: More DEA Information about Registrants' Controlled Substances Roles Could Improve Their Understanding and Help Ensure Access (2015) ("2015 GAO Report") at 43 ("… [A]dequate DEA communication with and guidance for its registrants are essential to help ensure that registrants take actions that prevent abuse and diversion but do not unnecessarily diminish patients' access to controlled substances for legitimate use because of their uncertainty about how to appropriately meet their CSA roles and responsibilities. … [S]ome … stakeholders said they needed improved communication and guidance regarding registrants' roles and responsibilities for preventing abuse and diversion under the CSA. … While providing additional guidance to registrants—particularly distributors and pharmacies—about their CSA roles and responsibilities cannot ensure that registrants are meeting them, by doing so DEA will have a greater assurance that registrants understand their CSA responsibilities.").

Rannazzisi,[89] DEA's policy not to advise when to file a suspicious order[90] and not to approve suspicious order monitoring programs.[91] Registrants repeatedly sought clarification concerning, among other things, the meaning of "suspicious order," due diligence, and how registrants should "know your customer" from DEA.[92] One reason why DEA did not provide clarification was because of litigations involving registrants and/or investigation of registrants.[93] Additionally, because of the changing drugs of interest, diversion tactics and other variables, DEA did not want to provide guidance.[94] Despite requests from industry, DEA consistently refused to provide

[89] CAH_MDL_PRIORPROD_DEA12_00010980, 10980 ("DEA does not approve or otherwise endorse any specific system for reporting suspicious orders. Past communications with DEA, whether implicit or explicit, that could be construed as approval of a particular system for reporting suspicious orders, should no longer be taken to mean that DEA approves a specific system.").

[90] Rannazzisi Dep. (Day 1) 45:19-46:7 ("A. It's DEA's policy that they do not advise when to ship or when to file a suspicious orders. That's a business decision that, under the regulations, is maintained by the .. distributor. Q. And this was the policy at DEA the entire time that you were the head of the Office of Diversion Control, correct? … [A.] It was the policy of the agency.")

[91] Rannazzisi Dep. (Day 1) 42:17-23 ("Q. But isn't it true that you affirmatively stated that it was DEA's policy not to approve any suspicious order monitoring programs? A. That was the position of the agency. And yes, that was stated in at least two of my letters to industry."), 282:4-8 ("Q. Well, let me ask it this way: Has DEA provided in written form your explanation and elaboration of what a suspicious order is to registrants? A. Not as far as I'm aware.").

[92] June 1, 2011 HDMA Letter to DEA, "Questions for the Drug Enforcement Administration (DEA) Regarding Requirements for Suspicious Orders Monitoring and Reporting Submitted by the Healthcare Distribution Management Association (HDMA) (US-DEA-00008565-76), at 1-2, 6, 9; July 2, 2013 HDMA Letter to DEA, "Questions for the Drug Enforcement Administration (DEA) by the Healthcare Distribution Management Association (HDMA) Submitted July 2, 2013 for Discussion July 31, 2013," (US-DEA-00008577-83), at 1-2, 5.

[93] Prevoznik Rule 30(b)(6) Dep. (Day 1) 200:24-201:15 ("Q. … This morning you told me that for the 2010-2013 time period, because of litigation and other things, there were not necessarily briefings or distributor conferences held in that time period correct? A. There were -- we had stopped with the distributor initiative and we had stopped with the conferences with the wholesalers, yes. Q. In 2010 to 2013? A. Right. Q. And you told me the main reason was because of litigation and investigations, right? A. Correct.").

[94] Wright Dep. (Day 1) 106:6-22 ("It couldn't provide [guidance]. Because it is fluid, and there are too many variables, too many anomalies, too many situations. And what is the drug tomorrow? What is the problem tomorrow? Right now we started this internet with Hydrocodone. You tell me what the problem is today . . ."), 118:11-119:3 ("Fentanyl. We went from Hydrocodone to oxycodone, twice as potent, to fentanyl that is now dealing with micrograms. It is just so in – small, extremely, extremely potent. Their system – what was in Excessive was rigid. This is all you do. Under Suspicious this is the – there's too many variables. What is it? What is happening in Alaska? What's the drug of choice? Why? Compared to West Virginia, compared to Florida, compared to all the other – you have to look at all of this. And I can't. And DEA can't sit there and say, 'Oh, yeah. That works.' And then

additional guidance.[95] This lack of guidance was particularly problematic given that registrants were tasked with identifying suspicious orders during a time period when opioid prescriptions and the DEA's opioid quotas were increasing year after year.

7. Lack of Sufficient Guidance from DEA on Regulatory Requirements

DEA's refusal to provide guidance to industry on the definition of "suspicious order" and other topics resulted in the US Government Accountability Office issuing a report critical of DEA's responsiveness. In the report, GAO's "Recommendations for Executive Action" included the instruction that DEA "[s]olicit input from distributors, or associations representing distributors, and develop additional guidance for distributors regarding their roles and responsibilities for suspicious orders monitoring and reporting."[96] The GAO further noted in its report that "although DEA may not be able to provide guidance that will definitively answer the question of what constitutes a suspicious order or offer advice about which customers to ship to, DEA could, for example, provide guidance around best practices in developing suspicious orders monitoring systems."[97]

The Acting Administrator Chuck Rosenberg of DEA recognized DEA's lack of responsiveness to the questions and concerns of registrants in testimony before Congress. Specifically, Chuck Rosenberg testified "[a]nd we've been opaque. I think we've been slow. I think we've been opaque. I think we haven't responded to them. We're trying to issue guidelines more quickly. We're trying to answer their questions."[98] Similarly, Keith Martin, the ASAC in charge of the Cleveland DEA Office, testified that he would not know how a registrant would detect a suspicious order.[99] DEA's refusal to provide requested guidance to registrants on suspicious order monitoring and the definition of "suspicious order" hurt anti-diversion activities and resulted in confusion among registrants.

VII. THE EMERGENCE OF NEW DIVERSION TRENDS AND DEA'S RESPONSE

While I served as the Deputy Special Agent in Charge of the DEA's Miami Field Division from 2006-2007, I received weekly reports from the diversion program manager, commonly known as the DPM, of the DEA's diversion control group in Florida. At the time, the

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people migrate, economies change, so many factors coming. And if you're not ready to adapt to that, then you don't have a system.").

[95] June 22, 2016 Email from L. Milione to D. Ashley, "Follow-Up from HDA Board Meeting, at 1 (US-DEA-00008563-64); Wright Dep. (Day 1) 103:1-4 ("Q. Were you aware of some sort of guidance that issued from DEA about the Suspicious Ordering System? A. Not to my recollection.").

[96] 2015 GAO Report at 44.

[97] 2015 GAO Report at 27.

[98] Tr. of Senate Judiciary Hearing on DEA Oversight, Testimony of Chuck Rosenberg at 30 (June 22, 2016).

[99] Martin Dep. 218:3-21.

diversion control group's primary focus was an unprecedented growth in diversion by rogue internet pharmacies.[100]

Some of the rogue internet pharmacies (and pill mills) were DEA registrants, and, therefore, within the CSA's "closed system."[101] The diversion control group and special agents in Florida conducted investigations of internet pharmacies to determine whether they were breaking the law and brought criminal charges or sought immediate suspension orders where appropriate. I understand that rogue internet pharmacies were not unique to Florida, and the scale of the problem placed pressure on DEA's Office of Diversion Control to go outside the normal investigative and enforcement methods to address the new diversion trends.

On September 27, 2006, Joseph Rannazzisi, Deputy Assistant Administrator of the Office of Diversion Control, sent a letter to distributor registrants.[102] Mr. Rannazzisi stated, "DEA recognizes that the overwhelming majority of registered distributors act lawfully and take appropriate measures to prevent diversion."[103] This was consistent with DEA's belief that the major distributors were complying with their obligations. DEA recognized that "all registrants - manufacturers, distributors, pharmacies, and practitioners - share responsibility for maintaining appropriate safeguards against diversion."[104] Mr. Rannazzisi went on to write that the "maintenance of effective controls against diversion" language found in 21 U.S.C. § 823 creates a requirement that distributors "exercise due diligence to avoid filling suspicious orders that might be diverted into other than legitimate medical, scientific, and industrial channels" and "exercise due care in confirming the legitimacy of all orders prior to filling."[105] Mr. Rannazzisi

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[100] Prevoznik Rule 30(b)(6) Dep. (Day 1) 151:13-17 ("So it really changed the dynamic of diversion when it went to the internet."), 281:16-21 ("[Y]ou can go back to the internet days when … the pattern was all of the sudden products that were skyrocketing to the millions and hundreds of thousands that were never there."), 298:4-9 ("Back in 2005 when we started, that was when we were addressing the internet."); Rannazzisi Dep. (Day 1) 198:18-22 ("[W]e tried to focus on where the threat was and at that point in time [2005-2008], we had threats but it just seemed that the vast majority of the cases were Internet-based."); US-DEA-00004802 at slides 3 (describing emergence of diversion via the internet), 8 (contrasting "Cyber [Pharmacy] vs. Brick & Mortar [Pharmacy] Sales"); US-DEA-00020544, 20551 ("Between fiscal years 2006 and 2009, rogue Internet pharmacies were a major source of diversion.").

[101] Rogue Online Pharmacies: The Growing Problem of Internet Drug Trafficking, Hearing Before the S. Comm. on the Judiciary, 110th Cong., 110-472 (May 16, 2007) (testimony of Joseph Rannazzisi, Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration) at 18 ("MR. RANNAZZISI: … I can tell you that we have been shutting these [rogue internet] pharmacies down using our regulatory authority and immediate suspension authority. We have gone after them and immediately taken their registration so they cannot dispense and procure controlled substances.")

[102] MCKMDL00478906

[103] MCKMDL00478906, 478907.

[104] MCKMDL00478906, 478907.

[105] MCKMDL00478906, 478907.

further stated that a registrant "may not simply rely on the fact that the person placing the suspicious order is a DEA registrant," but must investigate any "suspicious circumstances."[106]

As discussed above, the CSA and its implementing regulations do not state that a registrant must conduct "due diligence" or investigate their customers, or refrain from shipping "suspicious orders" that they reported to DEA.[107] Mr. Rannazzisi's September 27, 2006 letter did not change the regulations. Instead, it vaguely implied that DEA was interpreting the CSA to require registrants to not ship some "suspicious orders" "that might be diverted into other than legitimate medical, scientific, and industrial channels." The letter also stated that registrants should "exercise due diligence" and "exercise due care in confirming the legitimacy of all orders prior to filling."[108] In other words, Mr. Rannazzisi's letter began the process of shifting expectations beyond the applicable regulations. This direction was not, however, expressed in clear or formal guidance and the DEA's primary focus, as expressed to registrants, was in addressing rogue internet pharmacies.

By its terms, the Controlled Substances Act imposed a duty on registrants within the closed system to take appropriate steps, as specified by DEA regulations, to ensure the safety and security of controlled substances while those substances are under the custody and control of the registrant.[109] Apart from requiring the registrant to make a good faith effort to ensure that its customer was properly registered (and thus, part of the closed system over which DEA has control),[110] the CSA and its implementing regulations imposed no obligation on registrants to prevent "downstream diversion" (i.e., diversion of controlled substances after such substances left the custody and control of the registrant) by investigating other registrants.[111] The regulation

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[106] MCKMDL00478906, 478907.

[107] 21 C.F.R. § 1301.74(b); Rannazzisi Dep. (Day 2) 534:4-9 ("Q. Do the words 'due diligence' appear in this regulation? A. No, ma'am."), 534:19-21 ("Q. Do the words "do not ship" appear in this regulation? A. No, ma'am."); Ashley Dep. 215:12-216:4 ("Q. Is [due diligence] explained in the federal regulation, [21 C.F.R. 1301.74]? … A. No."); Prevoznik Rule 30(b)(6) Dep. (Day 3) 1154:7-11 ("Q. Mr. Prevoznik, I think we've already established that the regulation does not explicitly say do not ship orders that you report as suspicious, right? A. I agree with that….").

[108] MCKMDL00478906, 478907.

[109] 21 U.S.C. § 823; 21 C.F.R. § 1301.71-.76; Rannazzisi Dep. (Day 2) 528:9-530:16 (testifying that requirements identified in September 2006 and December 2007 letters are not contained in the CSA).

[110] 21 C.F.R. § 1301.74(a).

[111] 21 U.S.C. § 823; 21 C.F.R. § 1301-71-76; Rannazzisi Dep. (Day 2) 534:4-24 ("Q. Okay. Now, in that section [21 C.F.R. § 1301.74], does the word or words 'know your customer' appear? A. No, ma'am. Q. Do the words 'due diligence' appear in this regulation? A. No, ma'am. Q. Do the words 'dispensing data' appear in this regulation? A. No, ma'am. Q. Do the words 'customer questionnaire' appear in this regulation? A. No, ma'am. Q. Do the words 'electronic order monitoring system' appear in this regulation? A. No, ma'am. Q. Do the words 'do not ship' appear in this regulation? A. No, ma'am. Q. Do the word 'dispensing data' appear

does not state that registrants must create or maintain "due diligence" files on any investigations of "suspicious orders" they identify.[112] The standards articulated in Mr. Rannazzisi's letter are not contained in the CSA or any DEA regulations interpreting the CSA.[113]

The September 2006 letter also contains a list of questions that a distributor registrant "may wish to inquire with the ordering pharmacy about."[114] These questions were focused on issues that had arisen in the context of rogue internet pharmacies. The list of questions seek information that DEA—in my experience—would attempt to obtain using law enforcement powers while building a criminal case against a registrant. For example, while it is illegal for a pharmacy "to sell controlled substances without a prescription," it is very unlikely that another registrant could determine whether a pharmacy was engaged in that conduct without using informants or engaging in undercover work. Given this context, it appears that DEA was attempting to shift its law enforcement role to registrants who did not have at their disposal the many investigatory tools available to DEA, such as administrative subpoenas, search warrants, wire taps, undercover personnel to conduct surveillance, or the ability to seize records and computers.[115]

On December 27, 2007, Mr. Rannazzisi sent a another letter to registrants.[116] In the letter, Mr. Rannazzisi referenced the suspicious order reporting requirement found in 21 C.F.R. § 1301.74(b) and wrote that "Registrants must conduct an independent analysis of suspicious orders prior to completing a sale to determine whether the controlled substances are likely to be diverted from legitimate channels."[117] Neither 21 U.S.C. § 823 nor 21 C.F.R. § 1301.71-76 state that a registrant is required to conduct an "independent analysis" of "suspicious orders" prior to

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in this regulation? A. No, ma'am."); Prevoznik Rule 30(b)(6) Dep. (Day 1) 212:1-4 ("Q. Today, does the regulation explicitly reference knowing your customer? A. No.").

[112] 21 C.F.R. §§ 1301.71-.76; Prevoznik Rule 30(b)(6) Dep. (Day 3) 1218:17-1219:10 ("Q. The DEA has certainly never issued any sort of guidance indicating that registrants must hold on to due diligence files for 15 years, correct? A. Yes. The only guidance I know is it's two years, two years for recordkeeping for the registrant. … Q. But there's no requirement that a due diligence file even be maintained, correct? A. Correct. Q. So the two-year rule does not apply to any due diligence files, per se, correct? A. Correct. I was just pointing out that within the regs, there is records for a two-year period."); Rannazzisi Dep. (Day 2) 555:7-11 ("Q. Is there any requirement in the DEA regulations or guidance to maintain due diligence documentation for a certain period of time? A. There's no requirements.").

[113] 21 U.S.C. § 823; 21 C.F.R. § 1301.71-76

[114] MCKMDL00478906, 478908.

[115] Martin Dep. 221:15-224:3 (describing various law enforcement powers available to DEA and confirming distributors and manufacturers are not empowered to use same because "[i]t's the job of law enforcement").

[116] CAH_MDL_PRIORPROD_DEA12_00010980.

[117] CAH_MDL_PRIORPROD_DEA12_00010980, 10980.

completing a sale of controlled substances to a DEA-registered customer.[118] This was the first time this guidance had been stated in a written communication to registrants from DEA, although some of the concepts had been previewed to the industry by Michael Mapes, Chief, DEA, Regulatory Section, and Chris Zimmerman, Vice President, Amerisource Bergin, at the DEA's Pharmaceutical Industry Conference on September 11-12, 2007.[119] There, DEA introduced "new customer due diligence" concepts, including "Know Your Customer" and "Do Not Ship."[120] DEA explained that "[r]eporting suspicious orders to DEA does NOT relieve the distributor of the responsibility to maintain effective controls to prevent diversion," "DEA cannot/will not tell a distributor: if an order is or is not legitimate; and/or if the distributor should or should not ship an order," and "Distributor must make a 'business' decision whether or not to ship the order."[121] DEA further explained that "'Know Your Customer' Due Diligence investigations [should be] completed on all **new** Retail and Wholesale Accounts" and "Retail chain pharmacies are exempted."[122] Amerisource Bergin and DEA explained that "[h]istorically Controlled Substance / Listed Chemical order monitoring has been based on a ship and report process," but new processes "[should] now [be] based on: identify, capture, investigate, and report suspicious orders; all **prior to shipment**."[123]

Mr. Rannazzisi also wrote in the December 2007 letter that "registrants that routinely report suspicious orders, yet fill these orders without first determining that order is not being diverted into other than legitimate medical, scientific, and industrial channels, may be failing to maintain effective controls against diversion."[124] Neither 21 U.S.C. § 823 nor 21 C.F.R. § 1301.71-76 state that a registrant is required to investigate a "suspicious order" prior to shipping.[125]

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[118] 21 U.S.C. § 823; 21 C.F.R. § 1301.71-76; Rannazzisi Dep. (Day 2) 528:9-530:16 (testifying that requirements identified in September 2006 and December 2007 letters are not contained in the CSA).

[119] Prevoznik Rule 30(b)(6) Dep. (Day 3), Ex. 29.

[120] Prevoznik Rule 30(b)(6) Dep. (Day 3), Ex. 30 (ABDCMDL00037184 at ABDCMDL00037190).

[121] Prevoznik Rule 30(b)(6) Dep. (Day 3), Ex. 30 (ABDCMDL00037184 at ABDCMDL00037188).

[122] Prevoznik Rule 30(b)(6) Dep. (Day 3), Ex. 30 (ABDCMDL00037184 at ABDCMDL00037190) (emphasis added).

[123] Prevoznik Rule 30(b)(6) Dep. (Day 3), Ex. 30 (ABDCMDL00037184 at ABDCMDL00037192) (emphasis in original).

[124] CAH_MDL_PRIORPROD_DEA12_00010980, 10981.

[125] 21 U.S.C. § 823; 21 C.F.R. § 1301.71-76; Rannazzisi Dep. (Day 2) 528:9-530:16 (testifying that requirements identified in September 2006 and December 2007 letters are not contained in the CSA); Prevoznik Rule 30(b)(6) Dep. (Day 1) 167:5-12 ("Q. Did the Controlled Substances Act contain any language that states whether or not a distributor could ship a suspicious order? A. It doesn't say specifically that. It does say that it needs to be -- it has to maintain -- maintain effective control against diversion."), 303:19-304:1 ("Q. You would agree with me that the

Mr. Rannazzisi also used the December 2007 letter to disavow earlier guidance and approvals that DEA had provided to registrants regarding their suspicious order monitoring by including the following statement: "DEA does not approve or otherwise endorse any specific system for reporting suspicious orders. Past communications with DEA, whether implicit or explicit, that could be construed as approval of a particular system for reporting suspicious orders, should no longer be taken to mean that DEA approves a specific system."[126]

As with the September 2006 letter, the standards articulated in Mr. Rannazzisi's December 2007 letter are not contained in the CSA or any DEA regulations interpreting the CSA.[127]

The investigatory standards articulated in both the September 2006 and December 2007 letters, including the shifting of investigatory responsibilities described above, are inconsistent with my understanding of the role of DEA and registrants. Historically, DEA conducted investigations to identify registrants that were diverting from the "closed system" and sought to remove their registrations in order to maintain the integrity of the system. Registrants were not expected to create private law enforcement teams—without actual law enforcement powers—to replace DEA's special agents and their enforcement powers.[128]

VIII. OPTIONS AVAILABLE TO ENHANCE DEA'S REGULATORY AND ENFORCEMENT EFFORTS

There were multiple legitimate options for enhancing DEA's regulatory and enforcement efforts in response to emerging drug diversion trends that did not require introducing new standards not contained within the CSA or DEA regulations interpreting the CSA.

A. DEA can request changes to laws

Congress—on its own or at the request of DEA, the President, the Attorney General, or another party—could have changed the CSA to expand the duties of registrants. DEA maintains an Office of Congressional Affairs, whose sole purpose to be the "primary point of contact for all communications and interactions with Members of Congress and their staffs."[129]

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statute itself does not contain the express instruction that a registrant should hold an order and not ship it if it determines it to be suspicious, correct? A. Correct.").

[126] CAH_MDL_PRIORPROD_DEA12_00010980, 10980.

[127] 21 U.S.C. § 823; 21 C.F.R. § 1301.71-76; Rannazzisi Dep. (Day 2) 528:9-530:16 (testifying that requirements identified in September 2006 and December 2007 letters are not contained in the CSA).

[128] Martin Dep. 221:15-224:3 (describing various law enforcement powers available to DEA and confirming distributors and manufacturers are not empowered to use same because "[i]t's the job of law enforcement").

[129] Drug Enforcement Administration, Congressional Affairs, https://www.dea.gov/congressional-affairs (last visited May 25, 2019).

Congress has acted before to change the CSA to address new drug abuse trends. For example, in 2000, Congress passed the Hillory J. Farias and Samantha Reid Date-Rape Drug Prohibition Act of 2000 in response to concerns that "[g]amma hydroxybuyric acid … [had] become a significant and growing problem in law enforcement."[130] In the Bill, Congress directed DEA to schedule gamma hydroxybuyric acid as a List I Chemical[131] and amended the CSA to grant DEA authority to write new regulations for the reporting of transactions by registrants[132] and to create "a special unit which shall assess abuse of and trafficking in gamma hydroxybutyric acid, flunitrazepam, ketamine, other controlled substances, and other so-called 'designer drugs' whose use has been associated with sexual assault."[133]

As another example, in 2008, Congress passed the Ryan Haight Online Pharmacy Consumer Protection Act of 2008 to address online pharmacies in response to the issues with rogue internet pharmacies described above.[134] This act amended portions of the CSA to address concerns related to internet pharmacies.[135] Within 6 months of passage of the act, DEA implemented new interim regulations to advise registrants on the new requirements included in the act.[136]

As yet another example, in 1996, Congress passed the Comprehensive Methamphetamine Control Act because "[t]he abuse of methamphetamine ha[d] increased dramatically since 1990."[137] This act amended portions of the CSA to address the manufacture, distribution, and sale of precursor chemicals[138] and directed the establishment of a "suspicious order task force" to develop "proposals to define suspicious orders of listed chemicals, and particularly to develop

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[130] H.R. 2130, 106th Cong. § 2 (2000).

[131] H.R. 2130, 106th Cong. § 3 (2000).

[132] H.R. 2130, 106th Cong. § 4 (2000).

[133] H.R. 2130, 106th Cong. § 8 (2000).

[134] H.R. 6253, 110th Cong. (2008).

[135] H.R. 6253, 110th Cong. (2008); Drug Enforcement Administration, Implementation of the Ryan Haight Online Pharmacy Consumer Protection Act of 2008, 74 Fed. Reg. 15596, 15596 (Apr. 6, 2009) ("The Ryan Haight Online Pharmacy Consumer Protection Act, which was enacted on October 15, 2008, amended the Controlled Substances Act and Controlled Substances Import and Export Act by adding several new provisions to prevent the illegal distribution and dispensing of controlled substances by means of the Internet.").

[136] Drug Enforcement Administration, Implementation of the Ryan Haight Online Pharmacy Consumer Protection Act of 2008, 74 Fed. Reg. 15596, 15596 (Apr. 6, 2009) ("DEA is hereby issuing an interim rule to amend its regulations to implement the legislation and is requesting comments on the interim rule.").

[137] S. 1965, 104th Cong. § 2 (1996).

[138] S. 1965, 104th Cong. § 401 (1996).

quantifiable parameters which can be used by registrants in determining if an order is a suspicious order which must be reported to DEA."[139]

In response to concerns that prescription drug diversion was a significant and growing problem in law enforcement, Congress could have, but did not, amend the CSA to introduce any new standards regarding due diligence by registrants, reporting of suspicious orders, or shipping of suspicious orders necessary to "maintain effective controls."[140]

B. DEA can write new regulations

To the extent DEA wanted the statements in the September 2006 and December 2007 letters to be new standards authorized by the existing CSA,[141] the DEA could have written new regulations that clearly described the rules to registrants.[142] As part of writing new rules, the rules would have been subject to notice and comment regarding their clarity and usefulness in combating diversion,[143] and if the regulations exceeded the statutory authority granted to DEA by Congress, they could have been challenged in court by the affected parties. However, it is my understanding that DEA has not released any new regulations regarding due diligence by registrants, reporting of suspicious orders, or shipping of suspicious orders since the original regulations were released in 1971.[144] DEA never released any new regulations that incorporated the standards set forth in the September 2006 and December 2007 letters.[145]

1. Suspicious Activity Reports

In contrast to the minimal guidance offered to registrants and the ever-changing landscape of DEA expectations with respect to the SOM requirement, other regulated industries benefit from clearer expectations and significant detail on what is required. By way of example,

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[139] S. 1965, 104th Cong. § 504 (1996).

[140] 21 U.S.C. § 823.

[141] MCKMDL00478906, 478907 ("to maintain effective controls against diversion as section 823(e) requires, the distributor should exercise due care in confirming the legitimacy of all orders prior to filling"); CAH_MDL_PRIORPROD_DEA12_00010980, 10981 ("registrants that routinely report suspicious orders, yet fill these orders without first determining that order is not being diverted into other than legitimate medical, scientific, and industrial channels, may be failing to maintain effective controls against diversion. Failure to maintain effective controls against diversion is inconsistent with the public interest as that term is used in 21 USC 823 and 824").

[142] 21 U.S.C. § 821 (granting Attorney General authority to write rules regarding manufacture, distribution, and dispensing of controlled substances); 28 C.F.R. § 0.100 (granting Administrator of DEA authority to do same).

[143] Rannazzisi Dep. (Day 1) 310:24-25 ("A regulation goes through notice and comment.").

[144] Prevoznik Rule 30(b)(6) Dep. (Day 1) 89:17-90:13 ("Q. And have either the statute or regulation been amended or altered since 1971 to your knowledge? A. No, they have not.").

[145] Prevoznik Rule 30(b)(6) Dep. (Day 1) 89:17-90:13.

let us consider the financial industry, regulated by the Bank Secrecy Act, Patriot Act, Money Laundering Control Act of 1986 and associated regulations. Together, these statutes and regulations obligate financial institutions to monitor their accounts for money laundering and other suspicious activity. They, along with their associated administrative guidance, detail the type of monitoring banks must engage in to be compliant. Banks have an obligation to report suspicious activity, but not to stop it. As long as a bank is generally compliant with the regulation, it will not be penalized for failing to report any particular suspicious transaction. There is no set definition of what constitutes suspicious activity; however, the agencies have issued examples and lists of red flag activity that should be considered by banks in monitoring.

The Bank Secrecy Act and related regulations require banks "to report any suspicious transaction relevant to a possible violation of law or regulation."[146] Banks must have policies "that are reasonably designed to detect and report instances of money laundering through those accounts."[147] The section includes details about the requirements of such a due diligence policy. These requirements include:

> At a minimum: (A) the development of internal policies, procedures, and controls; (B) the designation of a compliance officer; (C) an ongoing employee training program; and (D) an independent audit function to test programs.[148]

Suspicious activity reports (SAR) are required to be filed within 30 days of detection of suspicious activity.[149] Unlike for suspicious order monitoring under 21 C.F.R. §1301.74(b), there is a standard form for SAR reporting. Specifically, when transactions aggregate to at least $5000 and the bank knows, suspects, or has reason to suspect one of the following, the bank must report: 1) the funds are derived from illegal activity or intended to disguise funds from illegal activity, 2) the transaction is designed to evade regulatory requirements, or 3) the transaction has no apparent lawful purpose.[150] This regulation's outline of specific situations that have to be reported is in stark contrast to 21 C.F.R. §1301.74(b), which only states that suspicious orders include those of unusual size, pattern, or frequency without providing specific examples of what those terms may mean.

Similar specific guidance is offered to national banks, who must file a SAR in situations involving a federal crime. These specific situations include: 1) when the bank knows or suspects a federal criminal violation and the amount involved is $25000 or greater, 2) where a suspect can

[146] 31 U.S.C. § 5318(g)(1)

[147] 31 U.S.C. § 5318(i)(1)

[148] 31 U.S.C. § 5318(h)(1)

[149] 31 C.F.R. § 1020

[150] 31 C.F.R. § 1020.320

be identified and the amount involved is $5000 or greater, or 3) where the bank has substantial basis that bank-affiliated parties aided in the crime.[151]

Where transactions involve a foreign institution, bank are required to have risk-based policies designed to detect money laundering.[152] The regulation details specific factors that should be considered in such policies, including the type of account, nature of the foreign institution's business, nature and duration of the relationship between the regulated bank and the foreign bank, money laundering rules of the foreign jurisdiction, and the foreign banks record with respect to laundering. A periodic review ensures that activity is consistent with the stated purpose of the account.

Special due diligence requirements are placed on accounts with more than $1 million.[153] Regulation specifies details about the due diligence program, which must determine the identity of account owners, source of deposited funds, purpose of account, and review activity to ensure it is consistent with the stated purpose of the account.

Guidance for this industry was also a priority during the regulation promulgation process. The regulators stated that "determinations as to whether a report is required must be based on all the facts and circumstances relating to the transaction and bank customer in question."[154] However, they went on to give specific examples of activity that would need to be reported, and other examples where it would be more of a judgment call based on the specific facts.[155] In contrast under the CSA, DEA has refused to opine on whether activity is suspicious or whether a company's SOM program would meet DEA's expectations.

The Bank Secrecy Act is enforced by the Financial Crimes Enforcement Network (FinCEN). Its website provides additional guidance regarding compliance, including a page entitled Guidance with links to documents in which FinCEN has provided guidance on various questions, links to administrative letter rules of general interest, and links to advisories describing specific criminal schemes to look out for including specific red flags.[156] FinCEN also gives further guidance on what should be included on a SAR.[157]

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[151] 12 C.F.R. § 21.11

[152] 31 C.F.R. § 1010.610

[153] 31 C.F.R. § 1010.620

[154] *Requirements to Report Suspicious Transactions*; Final Rules, 61 Fed. Reg. 4326, 4329 (Feb. 5, 1996).

[155] *Requirements to Report Suspicious Transactions*; Final Rules, 61 Fed. Reg. 4326, 4329 (Feb. 5, 1996).

[156] https://www.fincen.gov/

[157] SAR Narrative Guidance; SAR Activity Review, Issue 22; SAR Instructions; Frequently Asked questions regarding the FinCEN suspicious activity report (SAR).

Additionally, the federal financial institutions examination Council (FFIEC)[158] puts out a manual guiding compliance with Bank Secrecy Act and anti-money laundering examinations. The manual provides further guidance on both SAR filing and customer identification requirements. The section on suspicious activity reporting describes methods used to monitor suspicious activity, including employee observation, responses to requests from law enforcement, and systems to monitor transactions. Of note, the manual states: "The decision to file an SAR is an inherently subjective judgment. Examiner's should focus on whether the bank has an affective SAR decision making process, not individual SAR decisions." The manual provides guidance on what constitutes an effective SAR decision making process, and notes that "banks are not obligated to investigate or confirm the underlying crime . . . Investigation is the responsibility of law enforcement."

The Patriot Act requires banks to "ascertain the identity of the nominal and beneficial owners of, and the source of funds deposited into, such account[159] . . ." Regulations set minimum standards for identifying and verifying the identity of customers applying to open an account, including consulting lists of known terrorists.[160]

Instead of simply telling banks, "know your customer," the regulation goes on to offer specific guidance. The bank must have written procedures regarding identifying account owners. The regulations specify that at a minimum, banks must have customers' name, date of birth, address, and tax ID number.[161] The regulations include a form that can be used to ensure compliance with the identity requirement.[162] The rules also specify verification methods, such as using a non-expired government ID or comparing provided information with a public database.[163]

Overall, and unlike suspicious order monitoring under the CSA, the combination of statutes, regulations, regulatory history, administrative guidance and industry guidance serve to equip those in the financial industry with the knowledge necessary to be in compliance. In particular, they provide details about how to determine whether activity is suspicious and what specific knowledge about customers is required.

C. DEA can offer specific guidance

Once DEA purported to introduce new standards without changing regulations in the December 2007 letter, DEA could have provided registrants with specific guidance on how it expected registrants to identify suspicious orders, investigate suspicious orders, investigate their

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[158] This institution includes members like the Federal Reserve, FDIC, OCC, National Credit Union administration, and CFPB.

[159] 31 U.S.C. §5318(i)(3).

[160] 31 U.S.C. § 5318(l).

[161] 31 C.F.R. 1020.220

[162] 31 C.F.R. 1010.230

[163] 31 C.F.R. 1010.230

customers, and/or determine which suspicious orders or customers should be rejected. The need for specific guidance was exacerbated by DEA's rejection of all earlier express and implicit guidance to registrants in the December 2007 letter.[164] However, DEA did not provide specific guidance. In fact, DEA did not even provide answers when registrants repeatedly sought guidance from DEA on these issues.[165] Instead, DEA instructed registrants that it was their responsibility to fill in the details, and if they got it wrong, as determined by DEA, they would face enforcement actions.[166] Moreover, the December 2007 letter stated that DEA would "not approve or otherwise endorse any specific system for reporting suspicious orders."

Members of the Office of Diversion Control have offered various reasons for their unwillingness to provide specific guidance, including they were not allowed to answer questions,[167] that they did not provide information regarding suspicious pharmacies because they

[164] CAH_MDL_PRIORPROD_DEA12_00010980. 10980 ("Past communications with DEA, whether implicit or explicit, that could be construed as approval of a particular system for reporting suspicious orders, should no longer be taken to mean that DEA approves a specific system.").

[165] Ashley Dep. 71:23-72:13 ("Q. Okay. Let's go to the second point, the second bullet point. HDA asked that the DEA update the, quote, letters to industry provided in 2006 and 2007. Do you see that? A. Yes. . . . Q. To your knowledge, were there updated letters to industry provided after 2007? A. I don't recall that."); US-DEA-00008563 (email received by DEA in June 2016 describing questions from HDMA regarding suspicious order monitoring that were sent to DEA in 2011 and 2013, but were never answered). June 1, 2011 HDMA Letter to DEA, "Questions for the Drug Enforcement Administration (DEA) Regarding Requirements for Suspicious Orders Monitoring and Reporting Submitted by the Healthcare Distribution Management Association (HDMA) (US-DEA-00008565-76), at 1-2, 6, 9; July 2, 2013 HDMA Letter to DEA, "Questions for the Drug Enforcement Administration (DEA) by the Healthcare Distribution Management Association (HDMA) Submitted July 2, 2013 for Discussion July 31, 2013," (US-DEA-00008577-83), at 1-2, 5.

[166] MCKMDL00478906, 478908 ("Distributors should consider the totality of the circumstances when evaluating an order for controlled substances, just as DEA will do when determining whether the filling of an order is consistent with the public interest within the meaning of 21 U.S.C. 823(e).").

[167] Wright Dep. (Day 1) 254:7-20 ("There -- there were questions about -- during the time frame early on a distributor initiative time frame -- A. Yes, sir. Q. -- 2005, 2006, 2007, DEA, yourself were receiving questions from distributors about how to set up their Suspicious Order Monitoring programs, correct? A. Correct. Q. And you had mentioned, as I understand your testimony, that you weren't in position to provide them that type of information; is that fair? A. Yes.").

were afraid of being sued,[168] and that they did not offer guidance because they were engaged in litigation with some registrants.[169]

Nonetheless, as noted above, DEA's refusal to provide guidance to industry resulted in the U.S. Government Accountability Office issuing a report critical of DEA and led the Acting Administrator of DEA to admit, "we've been opaque. I think we've been slow. I think we've been opaque. I think we haven't responded to them. We're trying to issue guidelines more quickly. We're trying to answer their questions."[170] DEA has also represented in testimony before the Senate Judiciary Committee that, "we recognize the importance of working with registrants – not just at workshops and conferences – but in writing that they can count on – to provide them all the information and, especially, the certainty that they need to be in full compliance, as they want to be and as we expect them to be."[171]

Even after DEA admitted that it needed to be less opaque and provide better guidance, it appears that the Office of Diversion Control remains unwilling to help some registrants who approach the DEA in good faith to ensure compliance with the regulations. This reluctance was highlighted in the testimony of Mr. Prevoznik, the Associate Section Chief of the Pharmaceutical Investigations Section of the Diversion Control Division. Mr. Prevoznik testified that if a registrant came to him and said, "I am trying to decide whether this order is suspicious," and asked DEA whether the order was suspicious, Mr. Prevoznik "would be extremely concerned … [b]ecause you are basically telling me that you … do not have the ability to … maintain effective guards against diversion if you're coming to us with that hypothetical. Which would be grounds for us to revoke your registration."[172] If Mr. Prevoznik's testimony represents current DEA policy, it means that registrants cannot ask questions about identifying suspicious orders without risking losing their registrations.

IX. THE LIMITED EFFECT OF INCREASED SUSPICIOUS ORDER REPORTING

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[168] June Howard Rule 30(b)(6) Dep. 49:2-9 ("Q. Was the threat of litigation, was that threat too scary for the DEA so that it decided it would stop sending the termination notices to distributors? … [A.] I believe it contributed to ceasing sending out the notifications.").

[169] Prevoznik Rule 30(b)(6) Dep. (Day 1) 200:24-201:15 ("Q. … This morning you told me that for the 2010-2013 time period, because of litigation and other things, there were not necessarily briefings or distributor conferences held in that time period correct? A. There were -- we had stopped with the distributor initiative and we had stopped with the conferences with the wholesalers, yes. Q. In 2010 to 2013? A. Right. Q. And you told me the main reason was because of litigation and investigations, right? A. Correct.").

[170] Tr. of Senate Judiciary Hearing on DEA Oversight, Testimony of Chuck Rosenberg at 30 (June 22, 2016).

[171] Oversight of the Ensuring Patient Access and Effective Drug Enforcement Act, Hearing Before the S. Judiciary Comm. (2017) (statement of Demtra Ashely, Acting Assistant Administrator, Diversion Control Division, Drug Enforcement Administration) at 8.

[172] Prevoznik Rule 30(b)(6) Dep. (Day 1) 292:22-293:18.

If registrants had filed more suspicious order reports it would not have had meaningful impact on preventing diversion because DEA already possessed ARCOS data on controlled substance transactions and DEA rarely made use of the suspicious order reports it did receive.

A. DEA Already Had Information on Potential "Suspicious Orders" in ARCOS

Distributors reported all transactions involving purchase or sale of prescription opioid medications to the ARCOS reporting system.[173] Through ARCOS, DEA can see each and every bottle of opioids that transferred from a manufacturer to a distributor[174] and distributor to a pharmacy, hospital or physician.[175] It can also monitor downstream transactions all the way to the retail level.[176]

ARCOS reporting tools allowed DEA to identify pharmacies or physicians that were receiving extraordinarily large volumes of narcotics; DEA did not need registrant's suspicious order reports to do that.[177]

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[173] Prevoznik Rule 30(b)(6) Dep. (Day 1) 326:8-329:19 (describing scope of information contained in ARCOS, and agreeing that it included "all of the distribution of prescription opioids by manufacturers to distributors," "all the distributions of prescription opioids from distributors to pharmacies or other retail outlets," and "each and every bottle of opioids that's transferred from a distributor to a pharmacy"); DEA, Automation of Reports and Consolidated Orders System, https://www.deadiversion.usdoj.gov/arcos/index.html (last visited May 25, 2019) ("ARCOS is an automated, comprehensive drug reporting system which monitors the flow of DEA controlled substances from their point of manufacture through commercial distribution channels to point of sale or distribution at the dispensing/retail level - hospitals, retail pharmacies, practitioners, mid-level practitioners, and teaching institutions.").

[174] Rannazzisi Dep. (Day 1) 24:23-25:1 ("Q. So, Mr. Rannazzisi, using ARCOS, DEA can see the number of opioids sold by manufacturers to distributors? A. Yes."); Prevoznik Rule 30(b)(6) Dep. (Day 1) 326:18-23 ("Q. Would ARCOS contain all of the distributions of prescription opioids by manufacturers to distributors? A. So the transactions for . . . manufacturer to a distributor? Yes.").

[175] Rannazzisi Dep. (Day 1) 25:2-25:5 ("Q. And using ARCOS, DEA can see the number of opioids distributed by distributors to pharmacies, hospitals and doctors? A. Yes."); Prevoznik Rule 30(b)(6) Dep. (Day 1) 326:24-327:4 (Q. Would ARCOS contain all the distributions of prescription opioids from distributors to pharmacies or other retail outlets? A. For those items, yes.").

[176] Rannazzisi Dep. (Day 1) 24:10-16 ("[A.] DEA can use that system to monitor transactions downstream. Q. And that's downstream from the manufacturers all the way to the retail level, correct? A. Yes. I believe so."); Wright Dep. (Day 2) 538:16-19 ("Q. ARCOS tells you how many pills have been distributed by a distributor to a pharmacy, doesn't it? A. Correct.").

[177] Wright Dep. (Day 2) 544:1-11 ("Q. -- you were using these ARCOS reporting tools to identify pharmacies having extraordinarily large prescriptions in narcotics, and you present that data to the distributors, correct? A. Yes, sir. Q. You didn't -- you didn't need distributors' suspicious order reports to do that analysis, did you? … [A.] No, sir."); Wright Dep. (Day 2) 541:3-543:6 and Ex. 49; DEA Announces Enhanced Tool for Registered Drug Manufacturers

Moreover, up until February 2018, registrants did not have any access to other registrants' ARCOS data.[178] Although this had been requested by registrants, DEA declined to share it.[179] Further, except for individual meetings with registrants, such as during the Distributor Initiative briefings, when DEA identified potential internet pharmacies using ARCOS data, DEA did not share with distributors when it learned of suspicious pharmacies through ARCOS.[180] For a brief period after the distributor briefing, DEA informed distributors when another distributor terminated or restricted sales of controlled substances to a particular registrant.[181] However, DEA ceased this practice in 2007.[182] DEA decided to stop sharing this information because it did not want to risk being sued by the identified registrants and because field office personnel were concerned that legitimate pharmacies were being identified as

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and Distributors to Combat Opioid Crisis (2019), https://www.dea.gov/press-releases/2019/02/26/dea-announces-enhanced-tool-registered-drug-manufacturers-and (last visited May 25, 2019) (describing DEA's implementation of an amendment to the CSA requiring DEA "to provide drug manufacturers and distributors with access to anonymized information through the Automated Reports and Consolidated Orders System (ARCOS) to help drug manufacturers and distributors to identify, report and stop suspicious orders of opioids and reduce diversion on sales to ultimate users").

[178] Wright Dep. (Day 2) 554:11-25 ("Q. But DEA, up until 2018, did not permit other distributors to see the ARCOS data so that they could determine how much of a … controlled substance was being shipped into a pharmacy by another distributor; isn't that correct? … [A.] Yes, sir."); DEA Announces Enhanced Tool for Registered Drug Manufacturers and Distributors to Combat Opioid Crisis (2019), https://www.dea.gov/press-releases/2019/02/26/dea-announces-enhanced-tool-registered-drug-manufacturers-and (last visited May 25, 2019) (describing DEA's implementation of an amendment to the CSA requiring DEA "to provide drug manufacturers and distributors with access to anonymized information through the Automated Reports and Consolidated Orders System (ARCOS) to help drug manufacturers and distributors to identify, report and stop suspicious orders of opioids and reduce diversion on sales to ultimate users").

[179] Rannazzisi Dep. (Day 1) 26:3-13 ("Q. Registrants requested ARCOS data from DEA at various times, but DEA declined to share it, correct? … [A.] Just answering the question in order … registrants have requested access to ARCOS … for that data. And they have been declined, yes.").

[180] Wright Dep. (Day 1) 96:23-97:4 ("Q. And you looked for these outliers and the anomalies in the registrants' ARCOS data? A. Yes. Q. Did you use any other resource to find these outliers and anomalies? A. Not to my recollection."); Wright Dep. (Day 2) 550:12-25 ("Q. After identifying a suspicious pharmacy is in the ARCOS data, did you ever inform distributors of the identification of that pharmacy? … [A.] No.").

[181] Howard Depo. 28:17-1 ("Q. Following the first of the distributor briefings in 2005, DEA established an e-mail group to announce actions taken by distributors to either discontinue or limit supply to customers. A. Yes. Q. And these termination notices identified customers distributors had discontinued or restricted business with, correct? A. Correct.").

[182] Howard Depo. 45:9-13 ("Q. And do you know when the DEA stopped sending termination notices to distributors? A. Based on the DEA records that I reviewed, it appears that it ceased in December 2007.").

suspicious.[183] Thus, DEA was in the unique position to combine information from multiple sources to see potential diversion at pharmacies in a way that no distributor could.

For example, if one distributor cut off a particular pharmacy, the pharmacy could start ordering from another. DEA could see this from the ARCOS data, but distributors could not. Accordingly, one way to stop a rogue pharmacy or pill mill from continuing to divert opioids would be for DEA to suspend its registration so distributors would know to stop business with that pharmacy or pill mill.

B. Suspicious Orders Reports Rarely—If Ever—Led to DEA Actions Against Registrants

Only a small fraction of suspicious order reports ever result in DEA actions against registrants. DEA received 1.2 million suspicious order reports from 2007-2018.[184] Between 2007 and 2017, DEA had 9,851 actions leading to registration revocation, including 254 immediate suspension orders and 638 orders to show cause.[185] Not all of these revocations were related to suspicious order reports, but even assuming that they were, it would still be the case that less than 1% of SORs result in revocation.[186] There are many possible reasons why

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[183] Howard Depo. 47:2-13 ("Q. Why did DEA stop sending the termination notices to distributors? A. Based on my review of the DEA records, it appears the notification process ceased because diversion investigators in the field expressed concern about the notification, and individuals on the listing were legitimate pharmacies or doctors and needed their product for legitimate medical purposes. Also, the threat of potential litigation. And -- that's it for now, if I can -- yeah."), 47:14-18 ("Q. And what were the concerns of the diversion investigators? A. That registrants that were identified had legitimate purposes for ordering product and they should not be blacklisted."), 47:19-48:3, 49:2-9 ("Q. Was the threat of litigation, was that threat too scary for the DEA so that it decided it would stop sending the termination notices to distributors? … [A.] I believe it contributed to ceasing sending out the notifications.").

[184] The Drug Enforcement Administration's Role in Combating the Opioid Epidemic, Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce, 115th Cong., 115-110 (2018) (Questions for the Record for Drug Enforcement Administration) at 93 ("DEA headquarters received 1,204,400 electronic SORs from 135 distinct registrants from 2007 to 2018."); Prevoznik Rule 30(b)(6) Dep. (Day 2) 556:7-11 ("Between 2007 and 2018 DEA received over 1.2 million electronic suspicious order reports from registrants, true? A. Yes.").

[185] Combatting the Opioid Crisis: Exploiting Vulnerabilities in International Mail, Hearing Before the Subcomm. on Investigations of the S. Comm. on Homeland Security and Governmental Affairs, 115th Cong., 115-317 (2018) (Questions for the Record for Drug Enforcement Administration) at 275 (containing chart of "Actions Leading to Registration Revocation").

[186] *Compare* The Drug Enforcement Administration's Role in Combating the Opioid Epidemic, Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce, 115th Cong., 115-110 (2018) (Questions for the Record for Drug Enforcement Administration) at 93 ("DEA headquarters received 1,204,400 electronic SORs from 135 distinct registrants from 2007 to 2018.") *with* Combatting the Opioid Crisis: Exploiting Vulnerabilities in

suspicious order reports may not yield action: (1) DEA is not obligated to investigate suspicious order reports,[187] (2) the suspicious order reports contain many false positives because DEA has only provided vague guidance on how to identify suspicious orders; (3) normal ordering patterns by a pharmacy that is not responsible for diversion of controlled substances may result in "orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency";[188] (4) exigent circumstances such as natural disasters may lead to "orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency";[189] (5) human error, including typos in orders or "fat fingers," may result in "orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency,"[190] and (6) determining whether an order reflects actual diversion is particularly challenging during a time period when DEA quotas were being increased and legitimate prescriptions were increasing. In addition, I understand from my experience and the testimony in this case that some enforcement agents as well as diversion investigators did not use suspicious order reports.[191] Instead, diversion investigators used ARCOS data that contained all transactions from a distributor or manufacturer.

International Mail, Hearing Before the Subomm. on Investigations of the S. Comm. on Homeland Security and Governmental Affairs, 115th Cong., 115-317 (2018) (Questions for the Record for Drug Enforcement Administration) at 275 (containing chart of "Actions Leading to Registration Revocation" for years 2007 to 2017 that add up to 9,851); Press Release, DEA, DEA Surge in Drug Diversion Investigations Leads to 28 Arrests and 147 Revoked Registrations (Apr. 2, 2018), https://www.dea.gov/press-releases/2018/04/02/dea-surge-drug-diversion-investigations-leads-28-arrests-and-147-revoked ("During that period, the DEA surged the efforts of special agents, diversion investigators, and intelligence research specialists to analyze 80 million transaction reports from DEA-registered manufacturers and distributors, as well as reports submitted on suspicious orders and drug thefts and information shared by federal partners, such as the Department of Health and Human Services. This resulted in the development of 366 leads to DEA field offices, 188 of (51 percent) resulted in active investigations by DEA's 22 field divisions."); Martin Dep. 228:21-229:11 (confirming that the press release noted that DEA analysis of 80 million transaction reports led to only 188 investigations).

[187] Wright Dep. (Day 1) 164:11-15 ("Does DEA have an obligation to investigate a suspicious order after it is reported by a distributor? … THE WITNESS: No.").

[188] 21 C.F.R. § 1301.74(b).

[189] 21 C.F.R. § 1301.74(b).

[190] 21 C.F.R. § 1301.74(b).

[191] Martin Dep. 131:17-25 ("Q. As ASAC of DEA Cleveland and through other work that you've done at DEA, you're familiar with what a suspicious order report is? A. Actually, no, because that is on the diversion side. . . . I've never seen a suspicious order report"); And the DEA's diversion investigators did not use such reports; Baker-Stella Dep. (Day 2) at 466:17-20 ("Q. In your work at TDS on any investigation have you ever used a suspicious order report? A. Not that I can recall."); Leonard Dep. (Day 3) at 399:18-20 (testifying that Leonard doesn't use suspicious order data).

Given DEA's limited historical use of suspicious order reports to initiate actions against registrants, there is no basis to conclude that registrants filing additional suspicious order reports would have resulted in a meaningful decrease in diversion. Indeed, Mr. Rafalski, a former diversion investigator, has testified that failing to report a suspicious order does not cause diversion.[192]

However, it is difficult to conclusively answer why suspicious order reports did not and still do not lead DEA to take actions against registrants; indeed, DEA does not even keep statistics about what percentage of suspicious order reports DEA converts into criminal indictments or convictions.[193] In contrast, it does maintain such statistics on its OCDETF cases.[194]

X. CONTRIBUTORS TO THE DRUG CRISIS OUTSIDE THE CONTROL OF REGISTRANTS

Drug abuse existed in the United States prior to the diversion of prescription opioids and will continue in the future regardless of the availability of prescription opioids. The current opioid epidemic is best understood in the context of a decades-long drug overdose epidemic that began at least as early as the 1970s. The drug overdose epidemic is fueled by drug trafficking organizations that have long distributed illicit drugs, including illicit opioids, outside the "closed system of distribution"; the introduction of highly potent and dangerous illicit fentanyl from international sources; and the decisions of individual bad actors that trafficked illicit opioids or diverted prescription opioids outside the controls of the defendant registrants.

A. Drug Abuse Existed Prior to Prescription Opioids.

Before OxyContin was released in 1996, illicit drugs were causing considerable nationwide problems. When I worked for the St. Louis Police Department in the 1970s and 1980s, illicit drug abuse caused major public problems that forced the City of St. Louis to devote substantial public resources to combatting and treating drug abuse. When I worked for the DEA in the 1980s, the 1990s, and the 2000s, the same illicit drug problems applied on a broader national scale.

As a result of the widespread problems posed by illicit drugs, during my time at DEA, illicit drugs were always the DEA's primary focus and prescription drugs were never a top

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[192] Rafalski Dep. (Day 1) 371:20-23 ("You'd agree that not reporting the suspicious order to DEA is not what causes diversion? A. That's correct.").

[193] Prevoznik Rule 30(b)(6) Dep. (Day 2) 583:16-584:9 ("Q. Okay. Do you know what percentage of suspicious order reports DEA converted into criminal indictments between 2007 and 2017? … [A.] I do not. Q. … So between 2007 and 2017, would you know what percentage of suspicious order reports DEA converted into criminal convictions? … [A.] I do not. … Q. Does DEA keep those kind of statistics? A. No, we don't.").

[194] Prevoznik Rule 30(b)(6) Dep. (Day 2) 584:10-16 (" Q. … You're aware that DEA keeps those kind of statistics, investigations initiated, indictments returned, convictions obtained on all of their OCDETF cases and reports them. Are you aware of that? A. Correct, yes.").

priority. This remained the case even after OxyContin was released in the 1990s because the addiction, the crime, and the violence associated with drugs has always centered on the drug dealers and the cartels who traffic illicit substances.

B. The Illicit Drugs and Drug Trafficking Organizations That Are Causing Problems Today Have Existed For Decades.

Since I first joined the St. Louis Police Department in the 1970s, heroin has posed problems throughout the United States and drug cartels have trafficked heroin across the Southwest Border.[195] Since I joined the St. Louis Police Department in the 1970s, drug dealers, drug traffickers, and international drug cartels have existed and distributed illicit drugs.

Throughout my entire career at the DEA, the focus of the DEA's enforcement efforts has been on international drug cartels, such as the Sinaloa Cartel in Mexico and the Cali Cartel in Colombia. The DEA's focus has always been on these international drug trafficking organizations because they are responsible for the majority of the illicit drug trade in the United States.

The cartels that distribute drugs to the United States typically sell many different types of illicit drugs. For example, the same Mexican drug trafficking organizations that traffic heroin, traffic methamphetamine, cocaine, and marijuana.[196] In addition, for as long as I can recall, cartels have manufactured counterfeit prescription drugs and diverted prescription drugs.

In many instances, foreign drug regulation is much looser than American drug regulation, which is why foreign drug regulations can have a substantial impact on the trafficking of prescription drugs into the United States. During my time at DEA, loose prescription drug regulation was a problem with pseudoephedrine, a common cold medicine which is often diverted to be used to manufacture drugs like meth. In Mexico and Canada, you could buy pseudoephedrine in bulk, unlike in the United States, which has restrictive regulations governing how much you can purchase.

Summit and Cuyahoga County have problems with heroin and Mexican drug trafficking organizations today and they have had those problems for decades.[197] This is unsurprising

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[195] Leonard Dep. (Day 3) 444:8-10 (testifying that there "was heroin prior to my birth"). And as several of Plaintiffs witnesses testified, it would exist whether or not another opioid was ever prescribed in the United States; Leonard Dep. (Day 3) 446:18-447:7 ("Q. And whether or not another prescription opioid is-- were ever prescribed, dispensed, again, in the United States, there would still be an issue with fentanyl and heroin? A. Yes. Heroin has been her for a century. I mean, heroin has been a problem for a long time.").

[196] OH-HIDTA_000989, 1001 (indicating that "Mexican DTOs remain the greatest threat to the Ohio HIDTA region" because they traffic "heroin, cocaine, marijuana, and . . . methamphetamine.")

[197] SUMMIT_000023567, 23607-23609 (describing heroin as a "high" threat to Summit County in 2005 and indicating that "Mexican Drug Trafficking Organizations are the primary transporters and distributors of Mexican Black Tar, and Brown powdered heroin into Ohio");

because it is consistent with my experience and my understanding of the longstanding drug trafficking problems along the Southwest Border.[198]

C. The Characteristics of the Illicit Drug Market

In my 23 years at DEA, I kept myself informed of drug trafficking trends and drug abuse trends so that I could identify priorities and threats and allocate resources effectively. During that time, I observed the following:

The rates of drug trafficking and drug abuse have been increasing for decades.[199] There are many reasons for this, including (1) the introduction of drugs that provide a relatively inexpensive and intense high, such as crack cocaine and heroin, (2) economic depression in specific parts of the country, (3) advances in technology including features such as encrypted internet servers and development of the "dark net" making trafficking easier and more difficult to detect, and (4) the increasing sophistication and organization of drug trafficking networks.[200]

Drug abuse is cyclical. It is common for a particular drug to surge, then disappear, and then spike again. For example, heroin was the dominant drug of abuse in the 1970s, crack and

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OH-HIDTA_003501, 003503 (defining heroin as "a significant drug threat to the Ohio HIDTA region" in 2002 and explaining that "Mexican black tar, Mexican brown powdered, and South American heroin are the most prevalent in Northern Ohio."); Martin Dep. 213:21-214:7 ("Q. And is it also common knowledge that it is the drug cartels that are moving those -- the heroin across that southwest border into the United States? . . . A. Yes. Q. And it's those same cartels or drug trafficking organizations that further move the heroin into the state of Ohio? A. Yes."), 320:20-321:3 ("Q. What's the second question? A. 'How are illegal opioids coming into the Cleveland area?' Q. And what was your response? A. 'The most known or common way is the Mexican cartels are bringing it up. They are using the same routes that they've been using for the last hundred years, same routes, different methods of concealment.'")

[198] Sheehan Hannan, *Our Epidemic, Fighting the Opioid Problem*, Cleveland Magazine (Sept, 8, 2018, https://clevelandmagazine.com/in-the-cle/our-epidemic/articles/our-epidemic-fighting-the-opioid-problem) (reporting that "Mexican cartels" are bring drugs up to Cleveland "using the same routes that they've been using for the last hundred years.").

[199] Hawre Jalal et al., *Changing dynamics of the drug overdose epidemic in the United States from 1979 through 2016*, SCIENCE MAGAZINE, Vol. 361 Issue 6408 (September 21, 2018) (concluding that the "U.S. drug overdose epidemic has been inexorably tracking along an exponential growth curve since at least 1979.").

[200] OH-HIDTA_003369, 3371-3372 (attributing Northeast Ohio's drug issues to "economic depression" and the "introduction of 'crack' cocaine in the mid-1980s, which allowed for a relatively inexpensive and intense high"); Sheehan Hannan, *Our Epidemic, Fighting the Opioid Problem*, Cleveland Magazine (Sept, 8, 2018, https://clevelandmagazine.com/in-the-cle/our-epidemic/articles/our-epidemic-fighting-the-opioid-problem) (reporting that cartels are employing different methods of concealment as well as increasingly utilizing the dark web).

cocaine were the dominant drugs of abuse in Northeast Ohio the 1980s and 1990s,[201] methamphetamine and cocaine were dominant drug of abuse in Northeast Ohio in the early 2000s,[202] heroin became the dominant drug in Northeast Ohio in the 2010s,[203] and there have been recent shifts towards cocaine and methamphetamine.[204] A prime example of the cyclical nature of drug abuse is fentanyl, which has come and gone in cycles in the early 1990s and the mid-2000s.[205]

Drug cartels drive drug availability and are sophisticated business enterprises that frequently adapt to increase their profitability. For example, traffickers have taken aggressive measures to push heroin, like offering free methamphetamine to dealers, in order to expand the market for heroin, which is a more profitable and potent drug.[206] Likewise, cartels are known to push particular drugs to address oversupplies.[207] To increase their profits, traffickers also market

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[201] OH-HIDTA_003369, 3371-3372 (highlighting the introduction of crack cocaine in the mid-1980s and 1990s as a reason to designate Ohio as a high intensity drug trafficking area)

[202] OH-HIDTA_003501, 3503 (identifying cocaine as "the greatest drug threat in the major metropolitan areas that comprise the five designated Ohio High Intensity Drug Trafficking Area (HIDTA) Counties."); Law Enforcement and the Fight against Methamphetamine: Improving Federal, State, and Local Efforts, Hearing Before the H. Comm. on Government Reform, 109th Cong., 109-103 (2005) (statement of John Sommer, Director, Ohio High Intensity Drug Trafficking Area (HIDTA)) at 23-24 (describing the situation in Ohio with methamphetamines as an "epidemic").

[203] OH-HIDTA_000701, 708 (identifying heroin as the greatest drug threat in Northeast Ohio in 2011).

[204] AKRON_000236206 (identifying an increased supply of cocaine and an increased use of methamphetamine in 2017 as possible causes for a dramatic reduction in opioid overdoses); OH-HIDTA_000989, 999 (reporting that the "Ohio HIDTA is experiencing an increase in the use, seizure and prescribing of stimulants."); Shane Hoover, *Has the opioid drug crisis peaked? Overdose deaths drop in Stark, Summit Counties*, AKRON BEACON JOURNAL, November 16, 2018 (reporting an increase in stimulants and quoting the Executive Director of the Ohio High Intensity Drug Trafficking Area as predicting that stimulants will be the next crisis).

[205] AKRON_001143207 (DEA bulletin discussing a 2005-2006 "fentanyl overdose epidemic"); SUMMIT_000023567, 23630 (discussing a fentanyl scare that occurred on the eastern coast in the 1990s); Martin Dep. 186:10-19 (expressing the opinion that cocaine, heroin, illicit fentanyl and carfentanyl, and methamphetamines are the greatest drug threats to Summit and Cuyahoga counties).

[206] OH-HIDTA_003369, 3373 (reporting a "growing tendency of . . . gang related groups, to supplement their cocaine shipments with heroin, in an obvious attempt to create a greater market for this poison."); CUYAH_012915194, 12915203 (reporting that heroin use is increasing because of "pressure from dealers to switch from crack and prescription drugs to more-profitable heroin"); OH-HIDTA_00989, 1001 (reporting that "Mexican DTOs in parts of Ohio are providing methamphetamine to dealers for free in order to sell them heroin.").

[207] AKRON_000236206 (reporting that "Mexican cartels have an oversupply of cocaine and are flooding the market with it.").

products that are cheaper to produce, easier to smuggle, and more profitable. Pressures like these are common when traffickers are looking to offload inventories of particular drugs, target new drug abusers, or market more potent and profitable products.[208]

It is common for drug traffickers to target the same clients with multiple different substances. Since traffickers' business model revolves around getting their clients high, cartels can change pricing and supply to affect what their clients purchase, which can have a substantial impact on the broader drug market and influence which drug is the dominant drug of abuse at a given time. This is especially so because it is common for drug abusers to abuse multiple drugs and switch between different substances.[209]

To increase profits, dealers often mix drugs with cheaper fillers to increase the weight of their drug for resale.[210] But fillers may alter the taste, texture, or effects of the drug.[211] To counteract that effect, dealers may mix the diluted drug with a more potent substance.[212] As a result, there is an extraordinarily wide variance in potency amongst the same illicit drugs sold by different dealers.

D. Cyclical Illicit Drug Choices

The fact that heroin is abused in Summit County and Cuyahoga County today is unsurprising. Although its prevalence has ebbed and flowed over time, heroin existed in Cleveland in the early 1990s[213] and has been abused for as long as I have worked in law enforcement. There was a heroin epidemic in the 1970s and I confronted heroin as a narcotics

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[208] CLEVE_2288891 (indicating that lacing marijuana with fentanyl "may be the next step cartels are taking to target new users to become fentanyl users."); CUYAH_012915194, 12915203 (reporting that heroin use is increasing because of "pressure from dealers to switch from crack and prescription drugs to more-profitable heroin")

[209] AKRON_001102789 (reporting that 88% of drug abusers use more than one substance); AKRON_000236206 (indicating that users are switching from opioids to non-opioids based on the availability of cocaine and meth); Shane Hoover, *Has the opioid drug crisis peaked? Overdose deaths drop in Stark, Summit Counties*, Akron Beacon Journal, November 16, 2018 (reporting that "[m]any individuals who die from overdoses . . . test positive for a mixture of prescription and street drugs, including cocaine, benzodiazepines, methamphetamine and opioids, such as fentanyl and carfentanil.").

[210] AKRON_001143207, 001143215 (reporting that "[d]rug traffickers typically mix a diluent with narcotics to increase the weight for resale").

[211] AKRON_001143207, 001143215 ("A side effect of a diluent is reducing the potency of the original substance, which may alter the 'taste,' texture, or effects of the drug.").

[212] AKRON_001143207, 001143215 (explaining that when fentanyl is being added to heroin, "fentanyl is so powerful that the heroin is being enhanced"). Martin 188:8-10 (noting that fentanyl can be made to look like Oxy 30's, Percocet).

[213] Douglas Montero, *The Comeback Drug; Police, Social Workers Fear Heroin 'Epidemic'*, PLAIN DEALER, November 15, 1992 (reporting that use of "heroin . . . in Greater Cleveland and in the United States is on the rise, and there is fear it may become the drug of the '90s.").

detective in St. Louis the 1970s. Heroin use receded while crack and cocaine use grew in the 1980s and 1990s,[214] but cycled back and supplanted crack and cocaine use in the late 2000s.[215] The trend is now moving towards cocaine and meth becoming the dominant drugs of abuse today, underscoring that the problem communities are facing today is an illicit drug problem and not just an opioid problem.[216]

Heroin distribution and purity increased throughout the 1980s, 1990s, and 2000s.[217] During that time, traffickers also reduced prices and pressured dealers both directly and through incentives to switch from other drugs like crack and meth to more profitable heroin.[218] Increased heroin trafficking, increased heroin potency, pressure from dealers, and decreased heroin prices have all contributed to a rise in heroin abuse and heroin-related crime.[219] Potency contributes to a drug's addictiveness, and lower pricing makes the drug more accessible and more appealing to drug users. In particular, the DEA observed in the 1990s that heroin's "increase in purity led to

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[214] OH-HIDTA_003369, 3371-72 (highlighting the introduction of crack cocaine in the mid-1980s and 1990s as a reason to designate Ohio as a high intensity drug trafficking area).

[215] OH-HIDTA_000701, 708 (identifying heroin as the greatest drug threat in Northeast Ohio in 2011).

[216] AKRON_000236206 (identifying an increased supply of cocaine and an increased use of methamphetamine in 2017 as possible causes for a dramatic reduction in opioid overdoses); OH-HIDTA_000989, 999 (reporting that the "Ohio HIDTA is experiencing an increase in the use, seizure and prescribing of stimulants."); Shane Hoover, *Has the opioid drug crisis peaked? Overdose deaths drop in Stark, Summit Counties*, Akron Beacon Journal, November 16, 2018 (reporting an increase in stimulants and quoting the Executive Director of the Ohio High Intensity Drug Trafficking Area as predicting that stimulants will be the next crisis).

[217] OH-HIDTA_003501, 3503 (reporting that the "distribution of heroin of all types . . . is increasing along with quantitates trafficked, purity levels, and reduced prices."); CLEVE_001484132, 1484133-1484135 (reporting that heroin is available in larger quantities and that heroin abuse has grown since 2007).

[218] OH-HIDTA_003501, 3503 (reporting reduced heroin pricing); Douglas Montero, *The Comeback Drug; Police, Social Workers Fear Heroin 'Epidemic'*, Plain Dealer, November 15, 1992 (reporting that the "reasons for the growing popularity of heroin are that its cheaper and more potent, and that its availability in the streets has increased"); CUYAH_012915194, 12915203 (reporting that heroin use is increasing because of "pressure from dealers to switch from crack and prescription drugs to more-profitable heroin"); OH-HIDTA_00989, 1001 (reporting that "Mexican DTOs in parts of Ohio are providing methamphetamine to dealers for free in order to sell them heroin.").

[219] OH-HIDTA_000701, 708 (reporting that "[i]ncreased heroin trafficking has resulted in a rise in heroin abuse and heroin related crime"); OH-HIDTA_003501, 3503 (reporting that the heroin user population is growing and that heroin availability is growing at reduced prices); CLEVE_001484132, 1484133-1484135 (reporting that heroin is available in larger quantities, that heroin abuse has grown since 2007, and that there are "high purity batches of heroin solid in certain markets"); CUYAH_012915194, 12915203 (reporting that heroin use is increasing because of "pressure from dealers to switch from crack and prescription drugs to more-profitable heroin").

an increase in the number of heroin users" because when "heroin is in higher purity, it can be snorted or smoked which broadens its appeal" because it reduces "the stigma associated with injecting."[220]

I am of the opinion to a reasonable degree of professional certainty that drug traffickers and dealers all played a very important role in causing heroin use to grow. Whereas the increased availability and purity of heroin directly caused increased heroin abuse, there is evidence that few non-medical prescription opioid users go on to use heroin and that few non-medical prescription opioid users started with a medically necessary opioid prescription.[221] And the vast majority of individuals who reported transitioning from prescription opioids or heroin, reported the misuse of another drug before prescription opioids.[222] It is consistent with my experience that is common for drug addicts to abuse and switch amongst various drugs.[223] It is also consistent with my experience that many heroin abusers initiate their use with heroin.

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[220] CLEVE_001484132, 1484139 (explaining that heroin's appeal broadened when heroin became pure enough that it could be snorted because many people "who would never consider injecting a drug were introduced to heroin by inhalation").

[221] CUYAH_002048206 (several treatment providers reporting that it is "rare for one of our clients to have started with a medically necessary opioid"); CLEVE_001484132, 1484139 (reporting that "only a small number (approximately 4 percent) of CPD abusers initiate heroin use"); CUYAH_001670519 (reporting "[i]ncreased use of heroin as an initiating opioid of abuse").

[222] *Reduce Prescription Drug Abuse*, INSTITUTE FOR BEHAVIOR AND HEALTH, https://www.ibhinc.org/reduce-prescription-drug-abuse ("Among 4,493 individuals treated for opioid addiction whose first exposure to opioids was through a prescription from their physician, notably 94.6% reported prior or coincident use of other psychoactive drugs. Alcohol was used by 92.9%, nicotine by 89.5% and marijuana by 87.4%, and excluding these top substances, fully 70.1% reported other prior or coincident drug use."); Pradip Muhuri, Joseph Gfroerer, and M. Christine Davies, *Associations of Nonmedical Pain Reliever Use and Initiation of Heroin Use in the United States*, CBHSQ Data Review (SAMSA) (Aug. 2013, https://www.samhsa.gov/data/sites/default/files/DR006/DR006/nonmedical-pain-reliever-use-2013.htm (reporting that 86.1 percent of prior nonmedical pain reliever users have a history of prior illicit drug abuse); Deni Carise et al, *Prescription OxyContin Abuse Among Patients Entering Addiction Treatment*, AMERICAN JOURNAL OF PSYCHIATRY (Nov. 1, 2007), https://ajp.psychiatryonline.org/doi/full/10.1176/appi.ajp.2007.07050252?url_ver=Z39.88-2003&rfr_id=ori%3Arid%3Acrossref.org&rfr_dat=cr_pub%3Dpubmed&) (reporting that 77% of OxyContin abusers had also taken cocaine).

[223] AKRON_001102789 (reporting that 88% of drug abusers use more than one substance); AKRON_000236206 (indicating that users are switching from opioids to non-opioids based on the availability of cocaine and meth); Shane Hoover, *Has the opioid drug crisis peaked? Overdose deaths drop in Stark, Summit Counties*, Akron Beacon Journal, November 16, 2018 (reporting that "[m]any individuals who die from overdoses . . . test positive for a mixture of prescription and street drugs, including cocaine, benzodiazepines, methamphetamine and opioids, such as fentanyl and carfentanil.").

Since drug dealers and drug traffickers, not pharmaceutical manufacturers and distributors, manufacture and distribute heroin in the United States, drug dealers and drug traffickers are a major contributor to heroin abuse in Northeast Ohio today. In particular, the Mexican drug trafficking organizations that ship heroin across the Southwest border are the primary source of the heroin in Summit County and Cuyahoga County.[224]

E. Drug Cartels and Dealers, Not Demand, Drive the Illicit Fentanyl Market.

Illicit fentanyl and carferntanil are the main cause of opioid problems in Northeast Ohio today.[225] Indeed, several reports describe fentanyl as the primary drug trafficking threat to Northeast Ohio,[226] while coroner reports show that fentanyl and carfentanil have been driving drug overdose deaths since 2014.[227] DEA has also publicly stated that "[w]hile a number of factors appear to be contributing to this public health crisis, chief among the causes is the sharp increase in recent years in the availability of illicitly produced, potent substances structurally related to fentanyl."[228] In fact, DEA has gone so far as to state in its drug information sheet on fentanyl that "[i]llicitly manufactured fentanyl is chiefly responsible for the current domestic crisis."[229] During my time at DEA, I had heard of fentanyl, but I had never heard of carfentanil, which was not on anyone's radar as a possible drug of abuse until its sudden appearance in 2016.[230]

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[224] SUMMIT_000023567, 23609 (reporting "Mexican Drug Trafficking Organizations" as the "primary transporters and distributors of Mexican Black Tar, and brown powdered heroin into Ohio" in 2005); OH-HIDTA_000937, 944 (reporting that the "primary source of the heroin being transported and sold in Ohio is Mexican DTOs in 2016); Sheehan Hannan, *Our Epidemic, Fighting the Opioid Problem*, Cleveland Magazine (Sept, 8, 2018, https://clevelandmagazine.com/in-the-cle/our-epidemic/articles/our-epidemic-fighting-the-opioid-problem) (explaining that the "most common way" drugs are coming into Cleveland is from :Mexican cartels").

[225] Martin Dep. 186:10-19 (agreeing that cocaine, heroin, illicit fentanyl, meth and carfentanil are the greatest drug threats to Ohio today); Kenneth Ball Dep. 247:23-248:2 (testifying that fentanyl and carfentanil tipped the Akron's drug problems over the edge).

[226] OH-HIDTA_000989, 997 (identifying "[f]entanyl and its analogues" as "the primary drug threat in the Ohio HIDTA Region" in 2017).

[227] AKRON_000206798 (overdose death investigation spreadsheet from 2014-2018 identifying fentanyl or carfentanil as the cause of death in the vast majority of drug overdose cases).

[228] Drug Enforcement Administration; Schedules of Controlled Substances Temporary Placement of Fentanyl-Related Substances in Schedule I, 83 Fed. Reg. 5188, 5188 (Feb. 6, 2018).

[229] Drug Enforcement Administration, Fentanyl Drug Information Sheet (2018), https://www.deadiversion.usdoj.gov/drug_chem_info/fentanyl.pdf (last visited May 27, 2019).

[230] Martin Dep. 282:4-11 (testifying that he first "became aware of carfentanil in approximately July of 2016"); SUMMIT_00132316 (reporting that the DEA in Cleveland's first carfentanil arrest occurred in November 2016); Greta Johnson ("Johnson") Rule 30(b)(6) Dep. 91:16-18 ("I don't know that any of us had heard of carfentanil until about 2016"); Derek Siegle ("Siegle")

Nonmedical fentanyl use in Summit County and Cuyahoga County is driven by illicit fentanyl use, not pharmaceutical fentanyl use,[231] and the source of illicit fentanyl is drug dealers, not pharmaceutical manufacturers and distributors.[232] A huge reason for the rise in fentanyl abuse is that it is being seen mixed in other drugs, including methamphetamine, cocaine, heroin, and counterfeit prescription drugs laced with fentanyl.[233]

Mexican drug cartels—the same cartels the DEA has historically investigated—are a primary source of illicit fentanyl.[234] The other principal source of fentanyl is China, where many fentanyl analogues were legal, and web-based trafficking is growing.[235]

Mexican fentanyl is generally shipped across the Southwest Border, and Chinese fentanyl is most often shipped by postal carrier, which can make fentanyl difficult, if not impossible, to interdict.[236] Fentanyl traffickers actually prefer to use the United States Postal Service ("USPS")

Dep. 121:5-23 (testifying that carefentanil caught the region by surprise and wasn't seen in the area until very recently.)

[231] CLEVE_000273623, 0273630 (November 2014 email in which the Commander of the Cleveland Narcotics Unit states that Mexican cartels are shipping fentanyl over the border and he does not believe the fentanyl problems are "coming from any kind of pharmaceutical diversion."); AKRON_001143207; 114208 ("DEA Reporting indicates that pharmaceutical diversion of fentanyl normally does not result in bulk fentanyl distribution.").

[232] Siegle Dep. 120:19-121:4 (reporting that the majority of fentanyl related problems are related to the illicit fentanyl shipped by drug trafficking organizations).

[233] Martin Dep. 188:2-11.

[234] OH-HIDTA_000989, 997 (identifying "Mexican DTOs" as the "primary source of the fentanyl being transported and sold in Ohio"); AKRON_001143207, 1143215 (identifying "at least one Mexican DTO" as the source of the fentanyl coming into the United States since 2013).

[235] AKRON_000344115 (noting that "the Chinese . . . may be complicit in the sale" of "carfentanil and fentanyl"); CLEVE_000189730 (explaining that the fentanyl "problem will continue to grow due to WEB based trafficking out of China, Asian & European countries."); CLEVE_2289957 (explaining that all of Cleveland's "fentanyl related cases point to Mexico or China"); Martin Dep. 320:23-321:24 (explaining that China and Mexico are the two sources of fentanyl into Northeast Ohio)

[236] Matt Paolino Dep. 109:5-11, 174:23-176:10 (discussing the shipment of fentanyl through the mail, and the difficulties law enforcement has in interdicting drugs through mail); Sheehan Hannan, *Our Epidemic, Fighting the Opioid Problem*, CLEVELAND MAGAZINE (Sept, 8, 2018, https://clevelandmagazine.com/in-the-cle/our-epidemic/articles/our-epidemic-fighting-the-opioid-problem) (discussing the difficulties of fentanyl interdiction, which is that you can order it on the internet and there are thousands of packages every day coming from China). Tackling Fentanyl: the China Connection, Hearing Before the Subcomm. on Africa, Global Health, Global Human Rights, and Internal Organizations of the H. Comm. on Foreign Affairs, 115th Cong., 115-169 (2016) (statement of Paule E. Knierim, Deputy Chief of Operations, Office of Global Enforcement, Drug Enforcement Agency) at 21 ("It is extremely difficult for the Department of Homeland Security (DHS), U.S. Customs and Border Protection (CBP), U.S. Immigration and Customs Enforcement (ICE), and Homeland Security Investigations (HSI), and the U.S. Postal

to send fentanyl because, unlike private carriers, USPS cannot collect advanced electronic data ("AED"), which would assist in tracking and identifying traffickers, for packages distributed to it from international sources.[237] It is also impossible to stop and combat without the help of Chinese authorities. China only recently began regulating fentanyl and its analogs as controlled substances, but China's new regulations will not have any practical impact on the drug's availability in the U.S. unless those laws are enforced.[238]

Fentanyl is a popular drug among trafficking organizations and dealers because it is cheap to produce, easy to smuggle, potent, and highly profitable.[239] Cartels have an incentive to market it and add it to other drugs because fentanyl is both cheaper and more potent than other substances, including cocaine and heroin.[240] Fentanyl also masks dilution, and is highly

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Inspection Service (USPIS) to address the [fentanyl] threat at ports of entry, due to the combination of: the questionable legal status of these substances, which are not specifically named in the CSA itself or by DEA through scheduling actions; the enormous volume of international parcel traffic by mail and express consignment couriers; and the technological and logistical challenges of detection and inspection.").

[237] Combatting the Opioid Crisis: Exploiting Vulnerabilities in International Mail, Hearing Before the Subcomm. on Investigations of the S. Comm. on Homeland Security and Governmental Affairs, 115th Cong., 115-317 (2018) (Staff Report) at 112 (describing AED); 114-115, 21 (noting that express consignment operators, such as UPS and DHL, are required to collect AED by law); 113 ("Despite the benefits of using AED to identify suspicious packages, the international postal community has failed to meaningfully adopt its use.").

[238] Sasha Ingber, *China To Close Loophole After U.S. Calls for Opioid Action*, NPR (Apr. 1, 2019, https://www.npr.org/2019/04/01/708801717/china-to-close-loophole-on-fentanyl-after-u-s-calls-for-opioid-action) (reporting that China had announced that it would begin regulating fentanyl analogues but that China's ability to enforce the law is a different question); *How Did Enough Fentanyl to Kill "Every Man, Woman, and Child in Cleveland" Reach the United States?*, 60 MINUTES (Apr. 25, 2019, https://www.cbsnews.com/news/how-did-enough-fentanyl-to-kill-every-man-woman-and-child-in-cleveland-reach-the-united-states-60-minutes/) (reporting on a criminal case in which U.S. authorities alerted China to an illegal fentanyl operation which China refused to shut down).

[239] AKRON_001143207, 1143210 (explaining that fentanyl is "cheaper to produce, more potent, highly profitable, and easier to smuggle across borders" than other drugs because you don't need fields to grow it).

[240] Drug Facts, *What is fentanyl?*, NATIONAL INSTITUTE OF HEALTH, https://www.drugabuse.gov/publications/drugfacts/fentanyl (explaining that "drug dealers are mixing fentanyl with other drugs . . . because it takes very little to produce a high with fentanyl, making it a cheaper option"); AKRON_001143207, 1143210 (noting that "fentanyl is uniquely poised to become the next 'big idea' on a criminal industrial scale" because it is "cheaper to produce, more potent, highly profitable, and easier to smuggle across borders"); Maggie Fox, *Why would anyone cut heroin with fentanyl? It's cheap, these researchers say*, NBC News (Dec. 4, 2008, https://www.nbcnews.com/storyline/americas-heroin-epidemic/why-would-anyone-cut-heroin-fentanyl-it-s-cheap-these-n943796) (reporting that dealers are cutting fentanyl with other drugs because its cheaper than heroin, smaller, lighter, and easier to smuggle).

addictive, making it the perfect adulterant for cartels to add when cutting other drugs like heroin.[241]

The more fentanyl is pushed by the cartels, the more fentanyl causes problems. Many of the dealers who sell cocaine also sell heroin, and cartels often chop and mix fentanyl and other drugs. As a result, increased fentanyl distribution increases the risk of the unintentional contamination of other drugs with fentanyl.[242]

Buyers often do not know whether they are buying fentanyl and many drug users are afraid of fentanyl because it poses a high risk of overdose.[243] In fact, there is no slang term for fentanyl, which indicates that consumers do not seek it out, and that the increased use fentanyl is being driven by drug traffickers and cartels.[244]

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[241] Drug Facts, *What is fentanyl?*, National Institute of Health, https://www.drugabuse.gov/publications/drugfacts/fentanyl (explaining that "drug dealers are mixing fentanyl with other drugs . . . because it takes very little to produce a high with fentanyl, making it a cheaper option"); AKRON_001143207, 1143210 (noting that "fentanyl is uniquely poised to become the next 'big idea' on a criminal industrial scale" because it is "cheaper to produce, more potent, highly profitable, and easier to smuggle across borders"); AKRON_001143207, 1143215 (noting that fentanyl is so powerful that it enhances heroin) Maggie Fox, *Why would anyone cut heroin with fentanyl? It's cheap, these researchers say*, NBC News (Dec. 4, 2008), https://www.nbcnews.com/storyline/americas-heroin-epidemic/why-would-anyone-cut-heroin-fentanyl-it-s-cheap-these-n943796 (reporting that dealers are cutting fentanyl with other drugs because it is cheaper than heroin, smaller, lighter, and easier to smuggle).

[242] Max Daly, The Truth About Drug Dealers Lacing Cocaine with Fentanyl, VICE NEWS (Apr. 5, 2019, https://www.vice.com/en_us/article/8xyzkp/the-truth-about-drug-dealers-lacing-cocaine-with-fentanyl) (explaining that cocaine is packaged and cut multiple times during the supply chain so it is inevitable that fentanyl will be mixed with other powders like cocaine that are packaged and cut alongside it); Annamarya Scaccia, *How Fentanyl is Contaminating America's Cocaine Supply*, ROLLING STONE (Oct. 9, 2018, https://www.rollingstone.com/culture/culture-features/fentanyl-cocaine-how-contamination-happens-735155/) (noting that fentanyl laced cocaine is likely the result of accidental cross contamination because sealers often package and cut different products on the same substances without properly cleaning those substances).

[243] Maggie Fox, *Why would anyone cut heroin with fentanyl? It's cheap, these researchers say*, NBC News (Dec. 4, 2008, https://www.nbcnews.com/storyline/americas-heroin-epidemic/why-would-anyone-cut-heroin-fentanyl-it-s-cheap-these-n943796) (reporting that many "opioid users are actively afraid of fentanyl and don't want it, because they know about the dangers of overdose"); AKRON_000236206 (identifying a growing awareness of "dealers and users" about fentanyl as a reason for decreases in drug overdoses.).

[244] Maggie Fox, *Why would anyone cut heroin with fentanyl? It's cheap, these researchers say*, NBC NEWS (Dec. 4, 2008, https://www.nbcnews.com/storyline/americas-heroin-epidemic/why-would-anyone-cut-heroin-fentanyl-it-s-cheap-these-n943796) (reporting the absence of "any street slang words for fentanyl" is an "indication that demand is not driving the increased use of fentanyl").

Fentanyl has come and gone before, and cartels largely use the same illicit drug distribution methods for fentanyl that they use for other drugs.[245]

F. Prescription Drug Trafficking Existed Before Prescription Opioids.

Based on the documents I have reviewed in this case and my experience in law enforcement, I am of the opinion to a reasonable degree of professional certainty that counterfeit prescription drugs and illicitly trafficked prescription drugs are a contributor to the drug crisis in Cuyahoga and Summit County today.

Recent intelligence from the DEA confirms that international drug cartels are currently manufacturing counterfeit prescription drugs containing fentanyl,[246] and I understand that Summit County and Cuyahoga County are having problems with counterfeit prescription drugs laced with fentanyl that are coming from drug cartels today.[247] In addition, I have reviewed sources indicating that international drug trafficking organizations have started to manufacture and sell counterfeit prescription opioid drugs, including OxyContin, to Northeast Ohio that are manufactured overseas.[248]

The fact that counterfeit prescription drugs and illicitly trafficked prescription drugs are causing problems today is not new and does not surprise me. During my tenure at the DEA, international drug cartels capitalized on loose prescription drugs laws in other countries to counterfeit prescription drugs and traffic them to the United States. In particular, I remember

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[245] AKRON_001143207 (DEA bulletin discussing a 2005-2006 "fentanyl overdose epidemic"); SUMMIT_000023567, 23630 (discussing a fentanyl scare that occurred on the eastern coast in the 1990s).

[246] Intelligence Brief, *Counterfeit Prescription Pills Containing Fentanyls: A Global Threat*, DRUG ENFORCEMENT AGENCY, July 2016, at pg 1 (reporting that "[h]undreds of thousands of counterfeit prescription pills, some containing deadly amounts of fentanyls have been introduced into U.S. drug markets, exacerbating the fentanyl and opioid crisis."); Martin Dep. 188:8-10 (testifying that the DEA has "seen pills that are in the form of Oxy 30s, Percocets, that are actually fentanyl"), 252:6-252:18 (testifying that the counterfeit pills DEA is seizing are coming from the cartels).

[247] Johnson Rule 30(b)(6) Dep. 263:2-14 (testifying that Summit County has had instances in which drug dealers have sold counterfeit prescription drugs last with fentanyl); Siegle Dep. 122:5-122:17 (testifying that "we have had instances where our task forces have seized what appear to be pharmaceuticals that are really fentanyl pressed to look like it."); Leonard Dep. (Day 3) 437:16-19 (testifying that counterfeit opioid pills are part of the opioid epidemic).

[248] Siegle Dep. 123:7-123:19 ("Q. Are there drug trafficking organizations that deal in prescription opioids, as far as you are aware? A. Yes . . . It's usually in combination with some other narcotic. Q. So a source for some of the prescription opioids being abused in Ohio HIDTA are drug trafficking organizations; is that fair? A. That's fair to say, yes."); Leonard Dep. (Day 3) 436:13-18 (testifying that drug trafficking organizations are trafficking and selling diverted prescription drugs).

cartels capitalizing on loose prescription drug laws in Mexico to manufacture methamphetamines from cold medicine.

For as long as I was in DEA, the prescription drug regulations in other countries have contributed to drug abuse so it is neither new nor surprising that the drug regulations in other countries are an important contributor to the problem of non-medical prescription opioid abuse in the United States today.

G. Much Diversion of Prescription Opioids Occurs Outside the Closed System of Distribution

The vast majority of registrants act lawfully and do not engage in diversion.[249] However, diversion can occur in many ways, including: thefts by employees from hospitals, doctors' offices, or nursing homes; armed robberies of pharmacies; night-time burglaries of pharmacies; hijackings of prescriptions in transit; use of forged or altered prescriptions; thefts from the home

[249] MCKMDL00478906, 478908 ("DEA recognizes that the overwhelming majority of registered distributors act lawfully and take appropriate measures to prevent diversion."); Examining the Growing Problems of Prescription Drug and Heroin Abuse, Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce, 113th Cong., 113-140 (2014) (testimony of Joseph T. Rannazzisi, Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration) at 76 ("I think that if you are talking about 99.5 percent of the prescribers, no, they are not overprescribing, but our focus is in rogue pain clinics and rogue doctors who are overprescribing."); Challenges and Solutions in the Opioid Crisis, Hearing Before the H. Comm. on the Judiciary, 115th Cong., 115-57 (2018) (testimony of Robert Patterson, Acting Administrator, Drug Enforcement Administration) at 32 ("But I go back to the fact that I look at the vast majority of doctors: 99.99 percent are all trying to do right by their patients."); Prevoznik Rule 30(b)(6) Dep. (Day 1) 401:5-17 ("Q. As to prescription opioids, DEA believes that the overwhelming majority of prescribing in America is conducted responsibly? A. Yes, correct. Q. And DEA has stated that 99.5 percent of prescribers do not overprescribe opioids? … A. I don't know that we've said 99.5 percent. I've heard the figure 1 to 2 percent."); Prevoznik Rule 30(b)(6) Dep. (Day 1) 403:14-19 ("Q. So my question for you, the initial question, was, DEA has publicly stated that 99.5 percent of prescribers are not overprescribing, correct? A. Correct."); Prevoznik Rule 30(b)(6) Dep. (Day 2) 445:1-446:1 ("THE WITNESS: With the pharmacy diversion awareness conferences, I was with Mr. Rannazzisi at those conferences. And when we did the presentation, so that was from -- when I joined -- when I went to headquarters in April 2012, Atlanta was the first PDAC that I went to. So from that point on, pretty much every time that we had a presentation, we would say 1 to 2 percent [of prescribers diverted opioids]. So that is the figure that I know of, 1 to 2 percent. … Q. Okay. Would you agree then that not all registrants distributed controlled substance to the 1 or 2 percent of prescribers who diverted opioids from 2005 to 2018? ... [A.] I would be speculating on that, but, yes."); Ashley Dep. 329:14-22 ("Q. In your, frankly, remarkable career of rising from a secretary all the way up to an executive at DEA, isn't it the case, Ms. Ashley, that the vast majority of registrants with whom you dealt were trying to comply with the CSA and the implementing regs? … [A.] I agree with that, yes.").

by family, friends, or strangers.[250] All of these types of diversion happen outside the closed system of distribution and outside of the control of registrants. In fact, DEA has repeatedly acknowledged that the "most frequent method of obtaining a pharmaceutical controlled substance for non-medical use" is from "friends and family … for free!!"[251]

H. Individual Bad Actors Responsible for Opioid-Related Problems in Cuyahoga County and Summit County

As examples of the trends and factors I describe above, there are numerous individual bad actors that are responsible for the opioid-related problems in Cuyahoga County and Summit County—including employees of the plaintiffs themselves. Appendix A provides a summary of individuals (who are not parties to this case) who have been indicted, convicted, sued, disciplined, or otherwise found or allegedly found responsible for misconduct involving prescription opioids or illicit opioids in Cuyahoga County or Summit County since 1996. This includes at least 42 medical doctors, medical clinics, and other prescribers who have engaged or allegedly engaged in conduct related to improperly prescribing or diverting prescription opioids; at least 17 pharmacies, pharmacists, and pharmacy technicians who have engaged or allegedly engaged in conduct related to improperly dispensing or diverting prescription opioids; at least 460 additional individuals who have engaged or allegedly engaged in conduct related to diversion of prescription opioids, such as theft, forgery of prescriptions, re-sale or gifting of prescription opioids received through a prescription, or the acquisition of multiple prescriptions through "doctor-shopping"; and at least 701 individuals have engaged or allegedly engaged in conduct related to trafficking of illegal opioids, including (among others) heroin, fentanyl, and carfentanil. The documents cited in Appendix A therefore show widespread illegal and

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[250] Drug Enforcement Administration, Controlled Substance and Legend Drug Diversion; A Law Enforcement and Regulatory Perspective, https://www.deadiversion.usdoj.gov/mtgs/pharm_awareness/conf_2014/sept_2014/rannazzisi.pdf (2014) (last visited May 29, 2019) at 162 (describing "Methods of Diversion" in presentation to pharmacists); Martin Dep. 191:3-196:19 (confirming that "theft of prescription opioids from a delivery truck," theft from a pharmacy," "theft from a hospital," "pill sharing," "doctor shopping," and "forged prescriptions" are all forms of diversion).

[251] Drug Enforcement Administration, Drug Trends, https://www.deadiversion.usdoj.gov/mtgs/pharm_awareness/conf_2012/march_2012/drug_trends_0329.pdf (2012) (last visited May 29, 2019) at 25; Drug Enforcement Administration, DEA Perspective: Pharmaceutical Use & Abuse, https://www.deadiversion.usdoj.gov/mtgs/pharm_awareness/conf_2013/august_2013/prevoznik.pdf (2013) (last visited May 29, 2019) at 14; Drug Enforcement Administration, DEA Perspective: Pharmaceutical Use & Abuse, https://www.deadiversion.usdoj.gov/mtgs/pharm_awareness/conf_2014/july_2014/prevoznik.pdf (last visited May 29, 2019) at 29; Drug Enforcement Administration, DEA Trends & Update, https://www.deadiversion.usdoj.gov/mtgs/pharm_awareness/conf_2017/aug5_2017/carrion.pdf (2017) (last visited May 29, 2019) at 27; DEA's 17th National Prescription Drug Take Back Day Yields Fruitful Results in Georgia (2019), https://www.dea.gov/press-releases/2019/05/06/deas-17th-national-prescription-drug-take-back-day-yields-fruitful (last visited May 29, 2019) ("Studies show that a majority of abused prescription drugs are obtained from family and friends, including from the home medicine cabinet.");

professionally improper conduct in Summit County and Cuyahoga County that is the direct cause of abuse of prescription opioids. Here are just a few examples:

1. Prescribing Practitioners

a) Dr. Gregory Ingram

Dr. Gregory Ingram, a medical doctor working at Akron General Medical Center's Emergency Department in Akron, Ohio, was indicted on May 28, 2015 in the Northern District of Ohio on charges including distributing oxycodone, hydromorphone, Roxicet, and tramadol outside the usual course of professional practice and not for a legitimate medical purpose, in violation of 21 U.S.C. §§ 841(a)(1) and (b)(1)(C). According to the indictment, Dr. Ingram traded the illegal prescriptions for money and sexual favors, including with contacts that he met at dancing and strip clubs, between November 2012 and October 2014. Dr. Ingram pled guilty to all charges, and his own sentencing memorandum acknowledged that "he had become the equivalent of a drug dealer." He was then sentenced to one year in prison.[252]

b) Dr. Lorenzo Lalli

Dr. Lorenzo Lalli, a medical doctor practicing in Cleveland, Ohio, pled guilty on June 16, 2014 to offenses including trafficking, for operating a pill mill out of his medical office and for selling prescriptions for powerful painkillers and other pharmaceutical drugs. On July 29, 2014, Dr. Lalli was sentenced to one year in prison and ordered to forfeit $220,000. Dr. Lalli had earlier (in November 2013) surrendered his medical license to the Medical Board in lieu of further investigation or formal disciplinary charges.[253] Dr. Lalli was identified in the 30(b)(6) deposition of Cuyahoga County, through designee Assistant Cuyahoga County Prosecutor James A. Gutierrez, as a doctor who was prosecuted for misconduct related to prescription opioids.

c) The Medical Care Group

The Medical Care Group, a medical clinic chain, which has had offices in Cleveland, North Olmsted, Parma, Euclid, and Warrensville Heights, Ohio, was fined $12,500 in April 2017 for charges relating to a doctor-employee's handing out prescription opioids without an examination or monitoring of the individuals requesting them.[254]

2. Pharmacies, Pharmacists, and Pharmacy Technicians

a) Michael Baker

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[252] MCKPUB00000068; MCKPUB00000071; MCKPUB00000065; MCKPUB00024537.

[253] CLEVE_001486342; MCKPUB00000304; MCKPUB00000306; MCKPUB00024546; Summit County & City of Akron, Ohio's Amended Responses and Objections to the Manufacturer Defendants' First Set of Interrogatories and the National Retail Pharmacy Defendants' First Set of Interrogatories, at 6.

[254] MCKPUB00000362; MCKPUB00000365; MCKPUB00003647.

Michael Baker was licensed to practice pharmacy in Ohio. During an investigation, video cameras recorded Mr. Baker stealing drugs at Heritage Square Pharmacy on two occasions on January 28, 2015. When confronted by investigators, Mr. Baker had oxycodone pills that had not been legally prescribed on his person and admitted that he had stolen hydrocodone and oxycodone from the pharmacy for at least one year. On August 5, 2015, the Board of Pharmacy indefinitely suspended Mr. Baker's license to practice pharmacy.[255] On September 12, 2017, Mr. Baker's license was reinstated subject to terms of probation.[256] In an interrogatory response, Plaintiffs Summit County and the City of Akron named Mr. Baker as a pharmacist who was investigated in August 2015 for the diversion of prescription opioids, in relation to Heritage Square Pharmacy.[257]

b) Robert J. Roth

Robert J. Roth was licensed to practice pharmacy in Ohio. Mr. Roth was indicted on February 28, 2018 for offenses including intentionally creating and/or knowingly possessing a false or forged prescription in violation of Ohio Rev. Code § 2925.25(B)(1). He was charged with forging a prescription for hydrocodone homatropine cough syrup on May 13, 2014, while he was a pharmacist at Parkway Pharmacy in Cleveland, Ohio. Mr. Roth pled guilty on June 26, 2018 in the Cuyahoga County Court of Common Pleas, and he was sentenced to six days of community control and one hundred hours of community service. Under his plea agreement, Mr. Roth also was required to surrender his pharmacy license and sell his interest in Parkway Pharmacy.[258]

3. Individuals and Entities Involved in Diversion of Prescription Opioids

a) Rebecca Jo Collen, R.N.

Rebecca Jo Collen, R.N. had her license to practice nursing indefinitely suspended by the Board of Nursing on July 31, 2015. While working as a nurse at the Cleveland Clinic in Cleveland, Ohio, Ms. Collen diverted fentanyl by using a sterile syringe to remove fentanyl from intravenous therapy ("IV") bags that were hung for administration to patients.[259]

b) Kathleen A. Burgan

Kathleen A. Burgan of Cleveland, Ohio pled guilty on February 7, 2014 in the Cuyahoga County Court of Common Pleas to offenses including deception to obtain a dangerous drug,

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[255] SUMMIT_002053458.

[256] MCKPUB00000727.

[257] Summit County and City of Akron, Ohio Plaintiff's Supplemental Responses and Objections to Distributor Defendants' Interrogatory Number 3 as Rewritten by Special Master David Cohen, at 5.

[258] CUYAH_000080214; MCKPUB00000807; MCKPUB00000808; MCKPUB00000810.

[259] OBN_MDL 1st Production 074923, at OBN_MDL 1st Production 076435; MCKPUB00005188.

namely Percocet. According to a police report, Ms. Burgan filled multiple fraudulent prescriptions for Percocet at a pharmacy in Cleveland, all printed on stock copy paper with black grease smudges; Detective John Prince noted his belief that the suspect or her co-conspirators "intentionally attempted to corrupt the prescriptions in order to make them look worn and draw less scrutiny from a diligent Pharmacist." Ms. Burgan was sentenced to one year of community control.[260]

c) Lisa A. Rzeszotarski

Lisa A. Rzeszotarski of New Franklin, Ohio pled guilty on March 16, 2015 in the Summit County Court of Common Pleas to deception to obtain a dangerous drug, namely oxycodone. She obtained controlled narcotics from at least 32 physicians in the Akron area over twelve months. Ms. Rzeszotarski was sentenced to one year in prison, suspended provided that she complete eighteen months of community control.[261]

d) Alexander Linton

Alexander Linton of Cuyahoga Falls, Ohio pled guilty on March 1, 2016 in the Summit County Court of Common Pleas to robbery of oxycodone. Mr. Linton robbed pharmacies in Stow, Cuyahoga Falls, and Akron, stealing oxycodone and oxymorphone pills at gunpoint. Linton was sentenced to twelve years in prison.[262] Plaintiffs Summit County and the City of Akron identified Mr. Linton as someone under investigation for diversion.[263]

4. Individuals and Entities Involved in Distribution and Sale of Illegal Opioids

a) Stephen A. Thomas

Stephen A. Thomas of Maple Heights, Ohio, a corrections officers at Cuyahoga County Jail, was indicted on May 16, 2019 in the Cuyahoga County Court of Common Pleas on counts including illegal conveyance of drugs of abuse onto grounds of a governmental facility,

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[260] CLEVE_004083991; MCKPUB00024731; MCKPUB00024733; MCKPUB00024736.

[261] AKRON_001283454; MCKPUB00025234; MCKPUB00025235-25237; MCKPUB00025238-25241.

[262] AKRON_000337173; AKRON_000337174; MCKPUB00025075; MCKPUB00025076; MCKPUB00025078; MCKPUB00025079; MCKPUB00025081; MCKPUB00025082; MCKPUB00025084; MCKPUB00025086; MCKPUB00025088.

[263] Summit County and City of Akron, Ohio Plaintiff's Replacement Supplemental Responses and Objections to Manufacturer Defendants' Interrogatory Nos. 1, 2, 3, 5, 8, 9, 11, 12, 13, 15, 20, 21, 26, 27, 28 & 29, at 240; Summit County and City of Akron, Ohio Plaintiff's Supplemental Responses and Objections to Distributor Defendants' Interrogatory Nos. 2, 3, 4, 8, 12, 14, 15, 16, 17, 23, 24, 27 & 29, at 41; Summit County and City of Akron, Ohio Plaintiff's Supplemental Responses and Objections to National Retail Pharmacy Defendants' Interrogatory Nos. 4, 7, 15, 16 & 19, at 28.

trafficking in a fentanyl-related compound, trafficking in heroin, and corrupting another with drugs.[264] Mr. Thomas is accused of smuggling heroin and a fentanyl-related compound into Cuyahoga County Jail for the purpose of selling it to inmates, and selling it to inmates including to Kelly Angle on January 18, 2019, who overdosed but lived, and David Sowell on May 8, 2019.[265] On May 8, 2019, Mr. Thomas was seen on surveillance video going into Mr. Sowell's cell and selling him the opioids; Mr. Thomas was arrested later that day.[266] Cuyahoga County Assistant Prosecutor Matthew Meyer said in a court hearing that investigators have evidence that Mr. Thomas was part of a larger drug- and contraband-smuggling ring.[267] The case against Mr. Thomas is pending.[268]

b) Antoin Austin

Antoin Austin of Euclid, Ohio pled guilty on July 24, 2018 in the Northern District of Ohio to conspiracy to distribute controlled substances, including fentanyl and fentanyl analogues, attempted possession with intent to distribute fentanyl, distribution of a controlled substance by means of the internet, advertising controlled substances by means of the internet, maintaining a drug-involved premises, and maintaining a drug-involved premises near a school.[269] From August 1, 2017 through March 28, 2018, Mr. Austin sold fentanyl on the dark web from his home.[270] Mr. Austin ordered thousands of deadly doses of fentanyl from China.[271] On November 5, 2018, Mr. Austin was sentenced to two years' imprisonment.[272]

c) Gerald Bowerman

Gerald Bowerman of Cuyahoga Falls, Ohio pled guilty on August 17, 2018 in the Northern District of Ohio to conspiracy to possess with intent to distribute fentanyl.[273] On April 17, 2018, law enforcement officers surveilled Mr. Bowerman coming and going from an Akron, Ohio residence. Law enforcement observed Mr. Bowerman carrying a package with him into the home. They executed a search warrant at the residence later that day and recovered pills on the kitchen counter next to an empty U.S. Postal Service package. The pills were stamped to look like oxycodone but were fentanyl and cutting agents. In announcing the indictment, U.S. Attorney Justin E. Herdman stated, "These arrests helped save at least 1,500 lives." At the same

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[264] CUYAH_002399328; MCKPUB00029992.

[265] MCKPUB00029986; MCKPUB00029992.

[266] MCKPUB00029988.

[267] *Id.*

[268] MCKPUB00029985.

[269] MCKPUB00006964; MCKPUB00006957.

[270] MCKPUB00006957.

[271] MCKPUB00006978.

[272] MCKPUB00006966; MCKPUB00006974; MCKPUB00006981.

[273] MCKPUB00013570.

time, Akron Police Chief Kenneth Ball described the defendants as "criminal predators [who] were willing to put so many at great risk by poisoning prescription drugs with fentanyl."[274] Mr. Bowerman is awaiting sentencing.[275]

d) Da'Nico D. Geter

Da'Nico D. "Dupree" Geter of Akron, Ohio has multiple convictions for trafficking illegal opioids. Mr. Geter pled guilty on August 12, 2014 in the Summit County Court of Common Pleas to trafficking in heroin, and he was sentenced to six months in prison. On April 7, 2016, Mr. Geter was convicted of trafficking in heroin, and he was sentenced to eighteen months in prison. On October 6, 2017, Mr. Geter was indicted in the Summit County Court of Common Pleas on multiple charges, including aggravated trafficking in drugs and possession of drugs, including fentanyl. The indictment was dismissed because Mr. Geter was indicted in the Northern District of Ohio on January 10, 2018. On March 23, 2018, Mr. Geter pled guilty to possession with intent to distribute carfentanil and possession of a firearm in furtherance of drug trafficking.[276] During sentencing, the judge noted that Mr. Geter was a "career offender," and the "organizer, leader, manager, or supervisor" of his drug trafficking operations. Moreover, the sentencing judge observed that Mr. Geter's criminal history showed that "each time [he's] been incarcerated, [he's] turned back to the same type of dealing."[277] Upon learning that Mr. Geter was pleading guilty, Akron Chief of Police Kenneth Ball said that "310 people have died as a result of drug overdoses in Akron since the start of 2016. Drug dealers like Da'Nico Geter are largely responsible."[278] Mr. Geter was sentenced on June 7, 2018 to 300 months in prison, including 240 months for the carfentanil offense.[279]

Dated: May 31, 2019

Larry Holifield

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[274] MCKPUB00013583.

[275] MCKPUB00013572; MCKPUB00013575; MCKPUB00013581.

[276] AKRON_000201619; MCKPUB00009238; MCKPUB00009240; MCKPUB00009241; MCKPUB00009242; MCKPUB00009244; MCKPUB00009245; MCKPUB00009246; MCKPUB00009248; MCKPUB00009249; MCKPUB00009250; MCKPUB00009252; MCKPUB00009254; MCKPUB00009235.

[277] MCKPUB00029398.

[278] AKRON_000325481.

[279] MCKPUB00026700; MCKPUB00009255; MCKPUB00009257; MCKPUB00009262; MCKPUB00009263.